

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

**(19) World Intellectual Property Organization
International Bureau**



(43) International Publication Date
21 February 2002 (21.02.2002)

PCT

(10) International Publication Number
WO 02/13703 A1

(51) International Patent Classification⁷: **A61B 17/11**

(21) International Application Number: PCT/US01/25113

(22) International Filing Date: 10 August 2001 (10.08.2001)

(25) Filing Language: English

(26) **Publication Language:** English

(30) Priority Data:		
09/638,805	12 August 2000 (12.08.2000)	US
60/255,635	13 December 2000 (13.12.2000)	US
09/851,400	7 May 2001 (07.05.2001)	US
09/915,226	23 July 2001 (23.07.2001)	US

(71) Applicant (for all designated States except US): VEN-
TRICA, INC. [US/US]; 5055 Brandin Court, Fremont, CA
94538 (US).

CREWS, Samuel [US/US]; 330 Nimitz Avenue, Redwood City, CA 94061 (US). **REO, Michael** [US/US]; 701 Baltic Circle, Unit 731, Redwood City, CA 94085 (US). **CARSON, Dean** [US/US]; 1652 Yale Drive, Mountain View, CA 94040 (US). **LEPULU, Keke** [US/US]; 117 Vera Avenue #7, Redwood City, CA 94063 (US). **GITTINGS, Darin** [US/US]; 520 South Bayveiw Avenue, Sunnyvale, CA 94086 (US).

(74) Agent: LYNCH, Michael; Hoekendijk & Lynch, LLP, 433 Airport Blvd., Suite 432, Burlingame, CA 94010 (US).

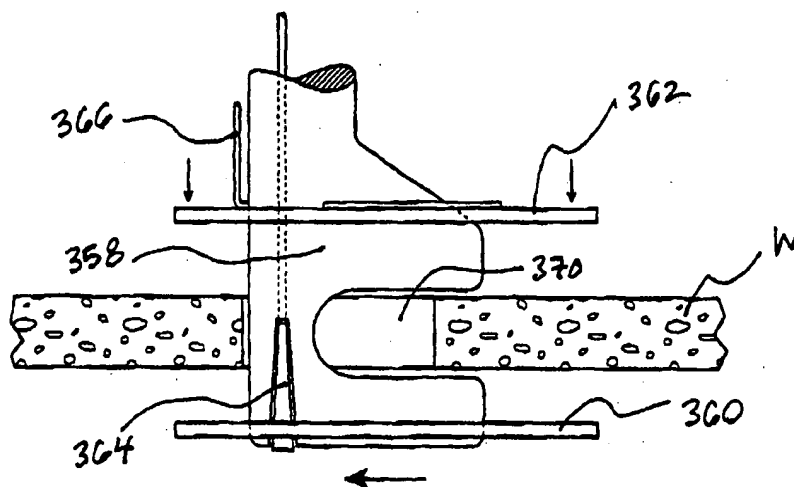
(81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, JP, KE, KG, KP, KR, KZ, LK, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(75) **Inventors/Applicants (for US only):** COLE, David
[US/US]; 1550 Lago Street, San Mateo, CA 94403 (US).

(84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European

[Continued on next page]

(54) Title: MAGNETIC COMPONENTS FOR FORMING ANASTOMOSES AND CREATING PORTS IN VESSELS



(57) Abstract: Methods and devices for forming an anastomosis between hollow bodies utilize magnetic force to couple anastomotic components (360, 362) and connect the lumens of the hollow bodies. End-to-side, side-to-side and end-to-end anastomoses can be created with or without a mechanical connection between the components (360, 362). The securing components (360, 362) have the ability to produce a magnetic field and may include materials or assemblies. A component (278, 280) may also be used to form a port into the lumen of a vessel, the component (278, 280) being attached to the vessel by mechanical and/or magnetic means. Magnetic components (278, 280) may include means (282, 284) for concentrating the magnetic flux between respective components (278, 280) to increase the attraction force, thereby enhancing the security of the anastomosis. Components (398, 400) having an occlusion surface may be used to close an opening in tissue, e.g., an atrial septal defect.

WO 02/13703 A1



patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

— before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

Published:

— with international search report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

MAGNETIC COMPONENTS FOR FORMING ANASTOMOSES AND CREATING PORTS IN VESSELS

CROSS-REFERENCE TO RELATED APPLICATIONS

5 This application is a continuation-in-part of application Serial No. 09/562,599, filed April 29, 2000 and entitled "Methods and Devices Using Magnetic Force to Form an Anastomosis Between Hollow Bodies," the entire subject matter of which is incorporated by reference herein.

BACKGROUND OF THE INVENTION

10 Field of the Invention

 The invention relates to methods and devices for forming anastomoses between two hollow bodies, creating magnetic ports in vessels, and closing openings in tissue, for example, atrial or ventricular septal defects.

Description of Related Art

15 Despite the considerable advances that have been realized in cardiology and cardiovascular surgery, heart disease remains the leading cause of death throughout much of the world. Coronary artery disease, or arteriosclerosis, is the single leading cause of death in the United States today. As a result, those in the cardiovascular field continue to search for new treatments and improvements to existing treatments.

20 Despite the considerable advances that have been realized in cardiology and cardiovascular surgery, heart disease remains the leading cause of death throughout much of the world. Coronary artery disease, or arteriosclerosis, is the single leading cause of death in the United States today. As a result, those in the cardiovascular field continue to search for new treatments and improvements to existing treatments.

25 Coronary artery disease is currently treated by interventional procedures such as percutaneous transluminal coronary angioplasty (PTCA), coronary stenting and atherectomy, as well as surgical procedures including coronary artery bypass grafting (CABG). The goal of these procedures is to reestablish or improve blood flow through occluded (or partially occluded) coronary arteries, and is accomplished, for example, by
30 enlarging the blood flow lumen of the artery or forming a bypass that allows blood to circumvent the occlusion. What procedure(s) is used typically depends on the severity and

location of the blockage. When successful, these procedures restore blood flow to myocardial tissue that had not been sufficiently perfused due to the occlusion.

Another proposed treatment places the target vessel, e.g., a coronary artery, in direct fluid communication with a heart chamber containing blood, for example, the left
5 ventricle. Blood flows from the ventricle into a conduit that is in fluid communication with the artery; as such, this treatment may be described as a ventricular bypass procedure. Benefits of this procedure include obviating the need to manipulate the aorta, for example, as is done when a side-biting clamp is used in a typical CABG procedure to create a proximal anastomosis between the bypass graft and the aorta. Clamping or otherwise manipulating the
10 aorta places the patient at risk in some cases due to the likelihood that such manipulation will release embolic material into the bloodstream. Some challenges associated with this procedure include delivering and deploying the conduit in the patient's body, properly positioning the conduit with respect to the heart chamber and the target vessel, and obtaining beneficial flow characteristics through the conduit and the target vessel.

15 A particularly challenging task that must be performed during CABG procedures (as well as some ventricular bypass procedures) is suturing the conduit to one or more vessels. As an example, one end of the conduit may be sutured to a source of blood, such as the aorta, a heart chamber or a blood vessel, while the other end of the conduit is sutured to the target vessel, such as a coronary artery or another blood vessel. The small
20 diameter of the vessels involved (typically from 1 mm to 4 mm) makes creating a handsewn anastomosis a highly technical and time-consuming procedure. The difficulty in forming the sutured anastomosis is exacerbated when access to the target vessel is restricted or limited, as in a minimally invasive or percutaneous procedure. This problem also arises in non-cardiovascular applications that utilize handsewn anastomoses, for example, treating
25 peripheral vascular disease or injury, creating AV (arteriovenous) shunts, etc.

While those in the art have proposed various anastomotic couplings intended to replace a sutured anastomosis, none has performed well enough to receive any significant level of acceptance in the field. Many of the proposed couplings penetrate or damage the target vessel wall acutely or chronically, do not remain patent, fail to produce a fluid-tight
30 seal between the conduit and vessel, or are simply too cumbersome and difficult to deliver or deploy.

While those in the art have proposed various anastomotic couplings intended to replace a sutured anastomosis, none has performed well enough to receive any significant

level of acceptance in the field. Many of the proposed couplings penetrate or damage the target vessel wall acutely or chronically, do not remain patent, fail to produce a fluid-tight seal between the conduit and vessel, or are simply too cumbersome and difficult to deliver or deploy.

5 Accordingly, there is a need in the art for methods and devices for forming a reliable anastomosis between hollow bodies in a relatively quick, easy and repeatable manner, for creating a port in a vessel for use in forming the anastomosis, and for closing openings in tissue, either permanently or temporarily.

SUMMARY OF THE INVENTION

10 According to one embodiment the invention provides a device for forming a magnetic port in a hollow body having a lumen. The device includes a component capable of producing a magnetic field and having an opening configured to be placed in communication with the lumen of the hollow body, and a housing disposed on an exterior of the component. The housing provides a substantially sealed enclosure containing the component and is
15 formed of a biocompatible material.

 Another embodiment provides a device adapted to be coupled to tissue using magnetic force. The device includes a first securing component that is capable of producing a magnetic field and is adapted to attract a second securing component also capable of producing a magnetic field. A magnetic force-increasing mechanism is provided for
20 increasing the magnetic force attracting the first and second securing components when they are positioned in proximity to each other.

 Another embodiment provides a device adapted to be coupled to a blood vessel having a lumen so as to produce a magnetic field adjacent the blood vessel. The device includes at least one securing component that is sized and configured to be secured to
25 a blood vessel having a lumen and is capable of producing a magnetic field. The securing component has an indicator that indicates the polarity of the magnetic field to a user carrying out a procedure on the blood vessel.

 Another embodiment provides a device for forming a port in a first hollow body having a lumen. The device includes a securing component having an opening adapted
30 to be placed in communication with an opening in the wall of the first hollow body e in communication with the lumen, and a mechanical attachment portion configured to secure the

component to the first hollow body in a desired position. The securing component is configured to produce a magnetic field adjacent the opening in the first hollow body.

Another embodiment provides a delivery device in combination with a component for forming an anastomosis. The combination includes at least one component having an opening adapted to be placed in communication with a lumen of a vessel in a patient's body, the component being capable of producing a magnetic field, and a delivery device including a support portion supporting the component. The delivery device has a retaining portion that is movable with respect to the support portion and is placed in a first position to retain the component and moved from the first position to release the component. The retaining portion is movable with respect to the support portion in either an axial or rotary direction.

Another embodiment of the invention provides a method for increasing the magnetic force between first and second anastomotic securing components. The method is performed by providing first and second anastomotic securing components each of which is capable of producing a magnetic field, the first and second securing components having respective openings adapted to be placed in communication with each other, and increasing the magnetic force between the first and second securing components by concentrating magnetic flux therebetween.

According to another embodiment of the invention a method for coupling a securing component to a target vessel in order to form a magnetic port communicating with a lumen of the target vessel. This method is performed by providing at least one securing component capable of producing a magnetic field and having an opening adapted to be placed in communication with the lumen of the target vessel, coupling the one securing component to the target vessel with the opening in the one securing component communicating with the target vessel lumen, and, prior to completing the coupling step, confirming the orientation of the polarity of the magnetic field.

Another embodiment of the invention provides a method for forming a magnetic port in a first hollow body located within a patient, the first hollow body having a lumen. The method is carried out by forming an opening in a wall of the first hollow body, the opening extending into the lumen of the first hollow body, providing a first securing component capable of producing a magnetic field and having an opening adapted to be placed in communication with the opening in the wall of the first hollow body, and coupling the first

securing component to the first hollow body by a mechanical attachment to form a magnetic port in the first hollow body.

BRIEF DESCRIPTION OF THE DRAWING FIGURES

Other features, aspects, benefits and advantages of the invention will be appreciated from the following detailed description of exemplary embodiments thereof taken in conjunction with the following Figures, wherein:

Figs. 1-5 are perspective views of anastomotic securing components constructed according to various embodiments of the invention;

Fig. 6 is a perspective view showing two hollow bodies adapted to be joined in communication via an end-to-side anastomosis;

Fig. 7 is a perspective view showing two hollow bodies adapted to be joined in communication via a side-to-side anastomosis;

Fig. 8 is a perspective view showing two hollow bodies adapted to be joined in communication via an end-to-end anastomosis;

Fig. 9 is a perspective view of the two hollow bodies shown in Fig. 6 along with an anastomotic system including anastomotic securing components constructed according to one embodiment of the invention;

Fig. 9A is a sectional view taken along line A-A in Fig. 9;

Fig. 10A is a section view similar to Fig. 9A but including alternative anastomotic securing components used to join the two hollow bodies;

Fig. 10B is a section view similar to Fig. 10A including other alternative anastomotic securing components for joining the two hollow bodies;

Fig. 10C is a section view similar to Fig. 10A but showing an alternative attachment between a hollow body and an anastomotic securing component;

Fig. 10D is a section view similar to Fig. 10C showing another alternative attachment between the hollow body and a securing component;

Fig. 11A is a transverse sectional view taken through an end-to-side anastomosis formed according to one embodiment of the invention;

Fig. 11B is a transverse sectional view taken through an end-to-side anastomosis formed according to another embodiment of the invention;

Fig. 12 is a perspective view showing two hollow bodies provided with anastomotic securing components constructed according to one embodiment of the invention,

the two bodies adapted to be joined via a side-to-side anastomosis;

Fig. 13 is a perspective view showing the two hollow bodies of Fig. 12 provided with anastomotic securing components constructed according to another embodiment of the invention;

5 Fig. 14A is a longitudinal sectional view taken through the side-to-side anastomosis formed according to the embodiment shown in Fig. 12;

Fig. 14B is a transverse sectional view taken through the side-to-side anastomosis formed according to the embodiment shown in Fig. 12;

Fig. 15 is a perspective view showing two hollow bodies provided with
10 anastomotic securing components constructed according to one embodiment of the invention, the two bodies adapted to be joined via an end-to-end anastomosis;

Fig. 16 is a perspective view showing the two hollow bodies of Fig. 15 provided with anastomotic securing components constructed according to another embodiment of the invention;

15 Fig. 17A is a plan view of one of the hollow bodies and securing components shown in Fig. 12;

Fig. 17B is a longitudinal sectional view of the hollow body and securing component shown in Fig. 17A;

Fig. 18A is a plan view of the hollow body of Figs. 17A-17B and a securing
20 component constructed according to an alternative embodiment of the invention;

Fig. 18B is a longitudinal sectional view of the hollow body and securing component shown in Figs. 18A;

Fig. 19A is a perspective view of the anastomotic securing component shown in Figs. 18A-18B, the component positioned in an opening in a hollow body with a lumen
25 having a stenosis disposed proximal to the opening;

Figs. 19B-19C show anastomotic securing components constructed according to further alternative embodiments of the invention, the components being shown positioned in the hollow body of Fig. 19A;

Fig. 20A is a perspective view of a delivery device constructed to one
30 embodiment of the invention, the device being shown in a first position;

Fig. 20B is a perspective view of the delivery device shown in Fig. 20A, the device being shown in a second position;

Fig. 21A is a perspective view of the delivery device shown in Fig. 20A with a

securing component constructed to one embodiment of the invention mounted thereon, the delivery device being shown in the first position;

Fig. 21B is a perspective view of the delivery device shown in Fig. 21A, wherein the device is shown in the second position as it is being manipulated to release the
5 securing component;

Figs. 22A-22F are sectional views schematically illustrating the delivery device shown in Figs. 20A-20B being used to deploy anastomotic securing components to form an end-to-side anastomosis according to one embodiment of the invention;

Fig. 23 is a perspective view of an exemplary application according to one
10 embodiment of the invention;

Fig. 23A is an enlarged view of a portion of the embodiment of Fig. 23 but showing a completed anastomosis;

Fig. 24 is a perspective view of another exemplary application according to another embodiment of the invention;

Fig. 24A is an enlarged view of a portion of the embodiment of Fig. 24 but showing a completed anastomosis;
15

Fig. 25 is a perspective view of an exemplary application according to still another embodiment of the invention;

Fig. 25A is an enlarged view of a portion of the embodiment of Fig. 25 but showing a completed AV shunt with two anastomoses;
20

Figs. 26A-26B are exploded perspective views of a device constructed according to one embodiment of the invention for forming a magnetic port in a hollow body having a lumen;

Fig. 26C is an assembled perspective view of the device shown in Figs. 26A-
25 26B;

Fig. 26D is a sectional view taken along line D-D in Fig. 26C;

Figs. 27A-27B are sectional views illustrating alternative constructions of the device shown in Figs. 26A-26D;

Fig. 28 is an exploded perspective view of two devices which are constructed according to another embodiment of the invention and are adapted to be coupled to tissue using magnetic force for forming a magnetic port in a hollow body having a lumen;
30

Fig. 29 is a sectional view taken through a vessel having a lumen, wherein the devices shown in Fig. 28 are coupled to the tissue of the vessel wall;

Fig. 30 is a sectional view of two magnets positioned in proximity to each other schematically illustrating the magnetic flux lines associated with the magnets;

Fig. 31 is a sectional view showing the two magnets of Fig. 30 provided with flux concentration mechanisms constructed according to another embodiment of the invention and schematically illustrating the magnetic flux lines associated with the magnets of the invention;

Fig. 32A is a perspective view of a device constructed according to another embodiment of the invention which is adapted to be coupled to tissue using electromagnetic force to form a magnetic port;

Fig. 32B is a perspective view of the device shown in Fig. 32A enclosed in a protective housing;

Fig. 33 is a perspective view of a device constructed according to yet another embodiment of the invention which is adapted to close an opening using electromagnetic force;

Fig. 34A is a sectional view taken through a target vessel having a lumen showing the device of Fig. 32B coupled thereto with a graft vessel shown (in phantom) prior to being anastomosed to the device;

Fig. 34B is a sectional view taken through a target vessel having a port defined by an anastomotic component communicating with the vessel lumen with the device of Fig. 33 positioned above the port prior to being used to close the opening;

Figs. 35A-35B are sequential sectional views taken through a target vessel having a lumen showing an anastomotic component constructed according to another embodiment of the invention being coupled to the wall of the vessel;

Figs. 36A-36B are, respectively, upper and lower perspective views of a device constructed according to another embodiment of the invention for forming a port in a vessel having a lumen, wherein the device has a mechanical attachment portion shown in a low profile or collapsed orientation;

Figs. 37A-37C are, respectively, upper plan, side elevation, and lower plan views of the device shown in Figs. 36A-36B;

Figs. 38A-38B are, respectively, upper and lower perspective views of the device shown in Figs. 36A-36B, wherein the mechanical attachment portion of the device is shown in a wide profile or expanded orientation;

Figs. 39A-39C are, respectively, upper plan, side elevation, and lower plan

views of the device as shown in Figs. 38A-38B;

Figs. 40A-40C are elevation views sequentially showing the device of Figs. 36A-39C being deployed in a vessel having a lumen;

Fig. 41A is a perspective view of a delivery device constructed according to another embodiment of the invention, wherein the device has a retaining portion shown in a first position to retain an anastomotic component;

Figs. 41B-41C are perspective views of the device shown in Fig. 41A but sequentially illustrating the retaining portion being moved to release the component;

Fig. 42A is a perspective view of a delivery device constructed according to still another embodiment of the invention, wherein the device has a retaining portion shown in a first position to retain an anastomotic component;

Figs. 42B-42C are perspective views of the device shown in Fig. 42A sequentially illustrating the retaining portion being moved to release the component;

Figs. 43A-43B are partial sectional views of the device shown in Figs. 42A-42C sequentially illustrating the device being used to couple an anastomotic component to a vessel;

Figs. 43C is a partial sectional view showing the anastomotic component in its final position;

Fig. 44 is a perspective view sequentially showing a flexible magnetic component constructed according to one embodiment of the invention being collapsed;

Figs. 45A-45B are perspective views illustrating a flexible magnetic component constructed according to one embodiment of the invention in its expanded and collapsed orientations, respectively.

Figs. 46A-46B shows alternative flexible magnetic components constructed according to additional embodiments of the invention;

Fig. 46C is a perspective view of a flexible component with a magnetic core constructed according to yet another embodiment of the invention, the component being adapted to substantially or completely close an opening in tissue or another component;

Fig. 46D is a perspective view of an alternative flexible magnetic component with a construction similar to the component of Fig. 46C but having an opening for placement in communication with the lumen of a vessel;

Fig. 46E schematically illustrates and exemplifies delivering the component shown in Fig. 46D in a low profile manner by way of a catheter or sheath;

Figs. 47A-47B are perspective views showing a device constructed according to another embodiment of the invention for closing openings in tissue in a restrained position for delivery and a partially deployed position, respectively;

Fig 47C is a fragmentary side elevation view of the device shown in Figs. 47A-47B but with the device fully deployed; and

Figs. 48A-48C are elevation views sequentially showing the device of Figs. 47A-47C being used to close a ventricular septal defect.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

One aspect of the present invention relates to methods and devices for forming an anastomosis between first and second (or additional) hollow bodies located in a patient's body, for example, a connection between a graft vessel and coronary or peripheral blood vessels, viscera, reproductive ducts, etc. The anastomosis places the hollow bodies, more specifically the lumens of the hollow bodies, in communication. In the case of blood-carrying bodies (or other hollow bodies that carry fluid) the anastomosis places the bodies in fluid communication. The hollow bodies being joined may comprise native or autologous vessels, vessels formed of synthetic material such as ePTFE or DACRON®.

Figs. 1-5 illustrate several exemplary embodiments of anastomotic securing components constructed according to the invention for use in forming an anastomosis between first and second hollow bodies. Fig. 1 shows a securing component 10 with an annular body and an opening 12 defined by the body. The component 10 is generally plate-shaped and circular in plan view with a constant (or substantially constant) thickness and width around its perimeter. The securing component 10 is sized and configured to be placed adjacent an opening of a first hollow body that has been prepared for anastomosis to a second hollow body. A second securing component would be placed adjacent an opening of the second hollow body for making the anastomotic connection.

Fig. 2 shows an elliptically-shaped, anastomotic securing component 14 with an opening 16. The securing component 14 is generally plate-shaped and the opening 16 is configured to provide the securing component 14 with larger end portions 18 than side portions 20. Fig. 3 shows a racetrack-shaped securing component 22 with an opening 24. As in securing component 14, the opening 24 provides securing component 22 with larger end portions 26 than side portions 28. Fig. 4 shows a securing component 30 with an opening 32, two end portions 34, 36 and two side portions 38. The securing component 30 has a generally

racetrack-shaped configuration, however, the end portion 36 is larger than the end portion 34 which provides the component 30 with an asymmetric configuration. Stated otherwise, the opening 32 is not centrally located with respect to the body of the component 30, unlike the openings 12, 16 and 24 of respective securing components 10, 14 and 22 shown in Figs. 1-3. Also, the end 36 provides a tapered leading edge for easier introduction into a hollow body such as blood vessel.

It will be understood that the specific shape and size of the securing components may be varied from the exemplary configurations depicted in Figs. 1-4. For example, the thickness or width of the securing component may vary along all or part of the body of the component. The anastomotic securing components of the invention are preferably, though not necessarily, plate-shaped, i.e., a first dimension D1 of the component is less than a second dimension D2 of the component (Fig 1). Typically, the lesser dimension corresponds to a thickness of the component while the larger dimension corresponds to a width or length of the component (or diameter in the case of Fig. 1). Minimizing the thickness of the securing component may be desirable for applications in which one or more components are placed within the lumen of a relatively small hollow body, e.g., a coronary artery, to reduce the amount of foreign material in the bloodstream and minimize flow impedance.

It will be noted that the securing components shown in Figs. 1-4 are generally flat; however, they could instead be curved or arcuate, or comprise a combination of flat and curved sections. Additionally, in the illustrated and preferred construction the shape of each securing component substantially corresponds to the opening therein. That is, the securing component and its opening preferably have complementary configurations (e.g., elliptical component, elliptical opening). Nevertheless, the securing component could have a non-complementarily-shaped opening. Finally, while each of the illustrated securing components includes only one opening, more than one opening could be used if desired.

According to preferred embodiments of the invention the anastomotic securing components are formed of or have incorporated therein a material capable of producing a magnetic field that acts to maintain the components in a desired positional relationship. The magnetic field results in the securing components maintaining the first and second hollow bodies in a desired position so as to be in fluid-tight communication. One or both securing components preferably has magnetic properties and may comprise permanent magnetic, ferro- or ferrimagnetic, or electromagnetic materials or assemblies.

Each of the securing components shown in Figs. 1-4 is formed substantially entirely of a suitable, magnetic field-producing material such that magnetic force may be generated over the entire area of the component. Fig. 5 shows an alternative embodiment wherein a securing component 40, which has an opening 42 and a racetrack-shaped configuration similar to securing component 22 of Fig. 3, has defined portions capable of producing a magnetic field. Specifically, the securing component 40 includes magnetic field-producing members 44 located at discrete areas which, in the illustrated embodiment, are at the ends of the component. The remaining areas 46 may thus be formed of a different material. It will be recognized that the members 44 could be located at alternative (or additional) areas of the securing component 40. An exemplary reason for providing the securing component 40 with areas 46 is to allow the use of a rigid magnetic material for the members 44 while still permitting the component to be partially or completely collapsed, for example, for delivery through a small incision or port, trocar, catheter, cannula, etc., by folding the areas 46.

Suitable materials that may be used to form an anastomotic securing component that is capable of producing a magnetic field include NdFeB (Neodymium Iron Boron), SmCo (Samarium Cobalt), and Alnico (Aluminum Nickel Cobalt). NdFeB is currently preferred for its force characteristics. The amount of force exerted will depend on various factors including the materials used, the size of the magnets and the number of magnets. In addition, different applications will call for different force ranges. For instance, it may be desirable to minimize the force as much as possible while still achieving a fluid-tight and secure attachment when treating small diameter blood vessels. As an example, in anastomosing coronary vessels, it is preferred to use anastomotic securing components that produce magnetic force in the area of less than 0.25 lbs, and more preferably approximately 0.15 lbs or less.

Figs. 6-8 depict first and second hollow bodies that have been prepared for anastomosis in three different manners. Fig. 6 shows a first hollow body 50 with an opening 52 that is adapted to be joined to an opening 54 of a second hollow body 56 to form an end-to-side anastomosis. The completed anastomosis places the lumens of the respective hollow bodies in communication. The opening 52 is formed in the wall of the first hollow body 50, for example, by incising or punching the tissue of the wall, while the opening 54 is defined by an end of the second hollow body 56. Fig. 7 shows a first hollow body 58 with an opening 60 adapted to be joined to an opening 62 of a second hollow body 64, thereby forming a side-to-

side anastomosis that places their lumens in communication. The openings 60, 62 are formed in the walls of the hollow bodies 58, 64, for example, as described above regarding opening 52. Fig. 8 shows a first hollow body 66 with an opening 68 adapted to be joined to an opening 70 of a second hollow body 72 to form an end-to-side anastomosis. Each opening 68, 70 is defined by an end its associated hollow body 66, 72.

Figs. 9 and 9A show first and second hollow bodies 74, 76 respectively provided with first and second anastomotic securing components 78, 80 which are used to create an exemplary end-to-side anastomosis according to one embodiment of the invention. As shown best in Fig. 9A, the securing component 78 includes two members 78A, 78B disposed on opposite surfaces of a wall of the first hollow body 74. The securing component 80 includes two members 80A, 80B disposed on opposite surfaces of an everted end of the second hollow body 76. The members forming each securing component 76, 78 may be held in a desired and preferably fixed relative position by magnetic force, with magnetic force also being used to hold the two securing components in position. The securing components 78, 80 are moved together from the position of Fig. 9A to create a fluid-tight anastomosis.

Figs. 10A-10D depict additional end-to-side anastomoses formed according to other embodiments of the invention. Fig. 10A shows a first securing component 82 coupled to a first hollow body 84 and a second securing component 86 coupled to a second hollow body 88. The securing components 82, 86 have a laminated structure comprising one layer of material capable of producing a magnetic field disposed between two outer layers of different material. In order to produce a magnetic field the components may comprise, for example, permanent magnetic, ferromagnetic, ferrimagnetic or electromagnetic materials or assemblies. Some exemplary materials that may be used include metals, polymers, ceramics, etc.

One example of this embodiment of the invention comprises a securing component having a middle layer of permanent magnetic material (e.g., NdFeB) and two outer layers of ferromagnetic material (e.g., 300 or 400 series stainless steel). The outer layers may be attached to the middle layer by suitable adhesive or magnetic force. One specific example of a securing component constructed according to this embodiment comprises a 0.008" thick inner magnetic layer and two 0.001" thick outer stainless steel layers. It will be understood that this aspect of the invention may be practiced using other materials or assemblies.

A benefit of a laminated construction is that it allows the thickness of the magnetic layer to be reduced because the other layer(s) will provide the assembly with the

necessary strength and integrity, even if the magnetic layer is very thin (which typically makes the brittle magnet more easily fractured). In the above example, the steel layers may be very thin yet still able to absorb the load, e.g., the tensile forces that arise during movement of the hollow body or adjacent tissue. The particular overall dimensions of the securing component, as well as the dimensions of individual layer (or layers if a multilayer construction is used) will of course depend on the application. (As examples, for the securing component 22 shown in Fig. 3, the thickness is preferably less than 0.040", and more preferably less than 0.020", e.g., approximately 0.015" or even less, e.g., 0.008".)

The ability to form a very thin securing component allows formation of an anastomosis between relatively small hollow bodies, e.g., coronary blood vessels. Further, the anastomosis can be formed between blood-carrying hollow bodies with one or more of the securing components located in the blood flow path while minimizing the foreign material exposed to blood.

Fig. 10B shows first and second securing components 90, 92 coupled to first and second hollow bodies 94, 96. The first securing component 90 comprises a single member 98 positioned within the lumen of the first hollow body 94 against the interior surface of the wall of the body adjacent an opening therein. The member 98 has a coating 100 substantially, and preferably completely, surrounding its exterior surface. It may be desirable in some applications to apply a suitable coating, or alternatively, a suitable surface treatment, to all or part of the anastomotic securing component. For example, if the first hollow body 94 represents a blood vessel such as a coronary or peripheral artery, the securing component 90 will be exposed to the blood flow path. As such, depending on the material used to form the member 98, it may be desirable or necessary to coat or otherwise treat its surface to promote better thrombogenicity and/or improve flow past the anastomosis site. Some exemplary materials that may be used to coat or otherwise treat an anastomotic securing component constructed according to the invention include Gold, Platinum, Titanium Nitride, Parylene, Silicone, Urethane, Epoxy, Teflon and Polypropylene.

Fig. 10C shows an embodiment wherein first and second securing components 102, 104 are coupled to first and second hollow bodies 106, 108. Each component 102, 104 comprises a single member formed, as explained above, of a magnetic, ferromagnetic, or electromagnetic material. This embodiment, instead of everting an end of one of the hollow bodies 106, 108, provides the first securing component 102 with a portion 110 configured to attach the end of the first hollow body 106. The portion 110 may take various forms, for

example, a DACRON® suture ring or bioadhesive. It will be recognized that the portion for attaching the hollow body may be located at different areas of the second securing component 104 than shown in Fig. 10C.

Fig. 10D shows an embodiment of the invention similar to that of Fig. 10C with first and second securing components 112, 114 coupled to first and second hollow bodies 116, 118. The means for attaching the first securing component 112 to the first hollow body 116 in this embodiment comprises an expandable member 120, such as a stent, disposed within the lumen of the first hollow body. The member 120 forces the end of the first hollow body 116 against the first securing component 112 to attach the elements in a fluid-tight fashion. It will be appreciated that the embodiments of Figs. 10C and 10D are only two of the various ways in which a securing component may be coupled to a hollow body with everting tissue of the hollow body.

Fig. 11A is a transverse sectional view taken through an end-to-side anastomosis created by first and second securing components 122, 124 which are positioned adjacent openings of first and second hollow bodies 126, 128. The securing components 122, 124 are plate-shaped (as described above) and generally flat. Fig. 11B shows first and second securing components 130, 132 constructed according to an alternative embodiment of the invention positioned adjacent the openings of first and second hollow bodies 126, 128. The securing components 130, 132 are also plate-shaped but, rather than being generally flat, are arcuate or curved. As can be seen, the curvature of the securing components 130, 132 maintains the first hollow body 126 in a substantially round configuration as compared to the more flattened-out shape it assumes when used with the flat securing components 122, 124.

The arcuate securing components 130, 132 preferably have complementarily or substantially complementarily radii of curvature to provide an even distribution of force and good sealing. The securing components of the invention could, however, have different degrees of curvature, the curvature of each being either constant or changing over the body of the component. Also, while the illustrated securing components 130, 132 extend over approximately 120°, other configurations that extend between 0° and 360° could be used if desired, for example, 180°. Finally, while Figs. 11A and 11B show, respectively, a pair of flat components and a pair of arcuate components, the securing components of each pair used to create the anastomosis may have dissimilar configurations to varying degrees.

Figs. 12 and 13 show other embodiments of the invention wherein first and second hollow bodies 134, 136 are respectively provided with securing components in order

to create an end-to-side anastomosis. The embodiment of Fig. 12 utilizes first and second securing components 138, 140 respectively positioned adjacent openings in the hollow bodies 134, 136. Each securing component 134, 136 includes a single member that may comprise one or more materials and one or more layers, as described above. The components may be
5 fixed by adhesive or other means or remain in position via magnetic force, as explained above. The securing components 138, 140 are positioned through openings formed in the wall of the hollow bodies 134, 136 and are located within the respective lumens L1, L2 thereof, as shown in Figs. 14A and 14B. Once joined the components 138, 140 form a fluid-tight anastomosis that places the first and second hollow bodies 134, 136 in communication.
10 If the hollow bodies 134, 136 are blood (or other fluid) carrying structures, the anastomosis places them in fluid communication and provides a fluid-tight seal.

The embodiment of Fig. 13 uses first and second securing components 142, 144 which are respectively positioned adjacent openings in the hollow bodies 134, 136 so as to be partially disposed within the lumens thereof. The opening in each hollow body may be
15 formed by making a surgical incision, removing tissue with a punch, etc. Each securing component 142, 144 includes a pair of members, and each member may comprise one or more materials and one or more layers. One member of each securing component 142, 144 is positioned within the lumen of its hollow body while the other member of the securing component is positioned on the exterior of the hollow body with tissue in between.

20 Figs. 15 and 16 show further embodiments of the invention wherein first and second hollow bodies 146, 148 are respectively provided with first and second anastomotic securing components in order to create an end-to-end anastomosis. Fig. 15 shows first and second securing components 150, 152 positioned adjacent respective openings of the hollow bodies 146, 148, each opening being defined by an end of a hollow body and extending into
25 the lumen thereof.

Each securing component 150, 152 includes a single member that may be constructed as described above. An end of each hollow body 146, 148 is passed through the opening defined in by a respective securing component and then is everted over the exterior of the component. As a result, joining the first and second securing components 150, 152 in
30 end-to-end fashion places the everted ends of the hollow bodies 146, 148 in sealed contact. In a case where the hollow bodies are natural blood vessels, such an anastomosis places the intimal surfaces of the vessels in contact.

The embodiment of Fig. 16 includes first and second securing components

154, 156 positioned adjacent the openings of hollow bodies 146, 148, respectively. The securing components 154, 156 each comprise a pair of members constructed as described above. The first securing component 154 includes one member 154A positioned around the exterior of the first hollow body 146 (with the end thereof everted), and another member
5 154B positioned around the opening defined by the end of the hollow body 146, the members 154A, 154B being held in place by magnetic force. The second securing component 156 has the same or a similar construction and includes members 156A, 156B which are positioned adjacent the end of the second hollow body 148. In the embodiments of Figs. 15-16 the securing components are not located within the lumen of either hollow body and thus are not
10 exposed to fluid or other substances contained therein or moving therethrough.

Another embodiment of the invention will be described with reference to Figs. 17A-17B. Fig. 17A shows a hollow body 160 with an opening 162 and an anastomotic securing component 164 positioned adjacent the opening. The securing component 164 is positioned within the lumen L of the hollow body 160 and has an opening 166. The opening
15 166 is aligned with the opening 162 in the wall of the body 160 as shown. In some instances, for example, when the securing component is forced through an incision in the wall, the tissue defining the opening 162 may move over the opening 166 of the securing component 164, as shown in Fig. 17B. As indicated by reference numeral 168 in Fig. 17B, this reduces the effective area of the securing component 164 that is available to communicate with a
20 second hollow body to which the hollow body 160 is anastomosed (not shown).

Fig. 18A-18B show the hollow body 160 with the opening 162 of Figs. 17A-17B, however, a securing component 170 constructed according to another embodiment of the invention is positioned adjacent the opening 162. The securing component 170 has an opening 172 and has a feature for maintaining the opening 162 open to flow. The securing
25 component 170 comprises a flange 174 and an extension 176 coupled thereto (or formed integrally therewith). As can be seen, the extension 174 prevents tissue defining or adjacent the opening 162 of hollow body 160 from migrating or springing back after delivery to reduce the cross-sectional flow area of the securing component 170.

Figs. 19A-19C show a hollow body 180 which may, for example, represent a
30 patient's coronary or peripheral artery the lumen of which is stenosed at S. In Fig. 19A, the hollow body 180 is provided with the anastomotic securing component 170 of Figs. 18A-18B by coupling the securing component to an opening in the wall of the artery, thereby forming a site for creating an end-to-side or side-to-side anastomosis. In Fig. 19B, the hollow body 180

is provided with an alternatively configured anastomotic securing component 182 which includes a flange 184 and a discontinuous or segmented extension 186 passing all or partly through the opening in the wall of the hollow body. Fig. 19C shows a securing component 188 with a multi-part construction including a flange 190 and a separate extension 192 which is received in the opening of the hollow body 180. It should be understood that these are only a few of the various constructions that may be employed in practicing this aspect of the invention.

The anastomotic securing components of the invention may be delivered and deployed in various ways. Figs. 20A-20B and 21A-21B depict somewhat schematically an exemplary delivery device 200 including a first portion 202 operatively coupled to a second portion 204. The first portion 202 is fixed to a shaft 206 while the second portion 204 is fixed to shaft 208 passing through a slot 210 in the portion 202. The first portion 202 defines a support ledge 212 and the second portion 202 similarly defines a support ledge 214. Fig. 20A shows the device 200 in a first position for retaining an anastomotic securing component of the invention. This position is shown in Fig. 21A wherein the ledges 212, 214 support a securing component 216 with the opening 218 of the component surrounding a boss 220 that extends upwardly from the ledges. The boss 220 is preferably used to help align the securing component on the support ledges 212, 214 and, if used in an application with an opening formed in a side wall of a hollow body, to restrain the surrounding tissue during placement.

Figs. 20B and 21B show the device 200 after it has been moved to a second position from the position of Figs. 20A and 21A. This is achieved by moving the shaft 208 in the direction of the arrows to slide the second portion 204 with respect to the first portion 202, which moves the support ledge 214 within the opening 218 of the anastomotic securing component 216 (Fig. 21B). This allows the user to separate the device 200 from the securing component 216 once the latter has been positioned at the desired location. As shown, depending on the relative dimensions and shapes of the respective components it may be necessary to rock or otherwise manipulate the device 200 relative to the securing component 216 in order to separate them.

It will be understood that the illustrated delivery device 200 is only one possible device suitable for use in placing the anastomotic securing components of the invention, and that it may be modified or replaced with a different delivery device or system. For example, the delivery device 200 could be altered so that both support ledges 212, 214 are moved with respect to the boss 220 (if used) in order to move fully out of contact with and

release the securing component. Any suitable material(s) may be used to construct the delivery device 200, it being appreciated using magnetic or ferromagnetic materials may result in magnetic interaction with the securing components, which may be desired to facilitate delivery of the components. The delivery device could also be constructed of nonmagnetic or ferromagnetic materials such as titanium, polymers, etc.

For sake of example, the creation of an anastomosis using the delivery device 200 and first and second securing components of the invention will be described with respect to Figs. 22A-22F. Fig. 22A shows the delivery device 200 with a first securing component 222 comprising two members 222A, 222B, the former member being supported by the ledges 212, 214 of the device 200 while the latter member is held above the ledges (e.g., by magnetic attraction to the device 200). The member 222A is being inserted into an opening in the wall of a blood vessel V with a stenosis S. The member 222A may be shaped or otherwise treated to ease insertion into the vessel lumen; for example, the leading edge of the member 222A may be formed as shown in the embodiment of Fig. 5.

Fig. 22B shows the one member 222A of securing component 222 positioned against the interior surface of the wall of the vessel and the other member 222B being moved toward the vessel wall. Fig. 22C shows the members 222A, 222B in position with the delivery device 200 remaining. Fig. 22D shows the device 200 being removed through first securing component 222, and Fig. 22E shows the securing component 222 remaining in the vessel wall to form what may be characterized as a magnetic port P. The securing component(s) may be provided with a surface treatment, such as coatings, roughened or treated areas, or mechanical projections, to enhance engagement with the wall of the hollow body.

The illustrated securing component 222 defines the magnetic port P and produces a magnetic field that may be used to couple another vessel to the port. In Fig. 22F, a graft vessel G provided with a second securing component 224 (which itself includes two members) is anastomosed to the port P with magnetic force holding the first and second securing components 222, 224 in a desired relative position. The invention may also be practiced using means for fixing the relative distance between the first and second securing components, for example, to prevent tissue being forced or squeezed from the space between the components due to the application of the magnetic force over time. Such means could comprise projections that extend directly between the components and act as a stop, or an intermediate element coupled to the components to restrain them against further movement.

It will be recognized that forming a magnetic port according to the invention may also be used in non-vascular applications, as well as applications not requiring an anastomosis to another vessel, for example, to provide an access to an area of a patient's body.

Several exemplary applications of the invention will be described with
5 reference to Figs. 23-23A, 24-24A and 23-25A. Fig. 23 is an anterior view of a human heart with a graft vessel G having one end 230 attached to the aorta, e.g., by a sutured anastomosis, and another end 232 prepared to be anastomosed to an occluded LAD. One securing component 234 is coupled to the end 232 of the graft G by any of the methods described above, and another securing component 236 is coupled to the LAD adjacent an opening
10 therein. The securing components 234, 236 are formed (at least in part) of materials capable of producing a magnetic field so that they may be attached as shown in Fig. 23A, thereby placing the graft G in fluid communication with the lumen of the LAD. The graft G could alternatively be attached to the aorta by an anastomotic system constructed according to the invention.

15 Fig. 24 shows another exemplary application of the invention applied to the heart shown in Fig. 23. A ventriculocoronary shunt S has one end 237 placed in the myocardium in fluid communication with the left ventricle LV. The shunt S is provided with a securing component 238 adjacent its other end while the LAD is provided with the securing component 236 of Fig 23. The shunt S is adapted to be coupled to the LAD via a side-to-side
20 anastomosis, therefore the securing component 238 is positioned in an opening in the side wall of the shunt (and the free end of the shunt is tied off at 240). Fig. 24A shows the completed anastomosis once the securing components 236, 238 have been coupled and remain in position via the magnetic field produced according to the teachings of the invention.

25 Figs. 25-25A illustrate yet another example of the many different applications of the invention, namely, the creation of an AV shunt. Fig. 25 shows a patient's arm including a number of the blood vessels located therein. An artery 242 is shown disposed in relatively close proximity to a vein 244. AV shunts are often created between an artery and vein in order to provide a site for repeatedly accessing a patient's vascular system, for
30 example, to treat dialysis patients. The shunt itself is typically formed of synthetic graft material and can withstand repeated needle sticks much better than a natural vein. An AV shunt 246 is created between the artery 242 and vein 244 by forming a side-to-side anastomosis using first and second securing components 248, 250. The shunt 246 is

preferably formed of ePTFE, DACRON® or another suitable synthetic graft material.

It should be appreciated that the applications of Figs. 23-23A, 24-24A and 23-25A represent several of many different uses for the invention. Other applications for the invention include, for example, neurological, urological and gastrointestinal procedures. As a further example, the invention could be used to form an anastomosis with an existing CABG graft that has partially or completely occluded over time, for instance, by placing the anastomotic securing components in the graft distal to the occlusion. In short, it will be recognized that the invention may be modified in varying degrees from the preferred embodiments illustrated and described specifically herein.

As noted above, it will be recognized that the invention may be used in many different procedures, for example, femoral-femoral, femoral-popliteal, femoral-tibial, ilio-femoral, axillary-femoral, subclavian-femoral, aortic-bifemoral, aorto-iliac, aorto-profunda femoris and extra-anatomic bypasses. In sum, the invention may be used to create an anastomosis with many different vessels, including, without limitation, the renal arteries, mesenteric vessel, inferior mesenteric artery, eroneal trunk, peroneal and tibial arteries.

Another embodiment of the invention will be described with respect to Figs. 26A-26D. A device for forming a port into a vessel (or for forming part of an anastomotic coupling) is indicated generally by the reference numeral 252 in Fig. 26A. The device 252 includes a member capable of producing a magnetic field, for example, permanent magnet 254, which preferably has an opening 256 adapted to communicate with a vessel lumen or other hollow body. The magnet 254 is received in a housing that, in this embodiment, comprises two elements configured for attachment to each other so as to enclose the magnet. One housing element 258 is generally dish-shaped with a rim 260 while the other housing element 262 is generally lid-shaped (as seen in Fig 26A).

Fig. 26B shows the magnetic member 254 disposed in the element 258 with the element 262 positioned above the assembly. Fig. 26C shows the element 262 affixed to the element 254 to form the housing and provide a sealed enclosure containing the magnetic member 254. This enclosure preferably forms a hermetically sealed environment that will protect the member 254 from external elements, e.g., blood or various bodily fluids, upon implanting the device 252 in a patient. The illustrated housing elements 258, 262 may be attached by any suitable means. For example, if constructed of metal laser welding may be used to join the housing elements. Other attachment means include adhesives, fasteners, etc.

The housing enclosing the magnetic member may of course be formed of a

unitary piece of suitable material, for example a metallic blank, or more than two pieces of material joined as described above. Fig. 26D is a sectional view of the device 252 shown in Fig. 26C illustrating the internal construction of the device, with lid element 262 resting on and secured to the rim 260 of dish element. Fig. 27A shows an alternative construction
5 wherein the member 254 is enclosed in a housing defined by a spool-shaped element 264 and a pair of lid-shaped elements 266 secured thereto, for example as described above. Fig. 27B shows yet another construction wherein the member 254 is enclosed in a housing defined by mating channel-shaped elements 268, 270 which are secured together to form the enclosure for the member 254. The housing enclosing the magnetic member is preferably formed of a
10 material that is a good to excellent conductor of magnetic flux. Exemplary materials are discussed above with respect to Figs. 26A-26C, as well as below in connection with Figs. 28-31.

Fig. 26C also shows (in phantom) a schematic representation of means for indicating the polarity of the magnetic member 254. The illustrated indicator 272 may take
15 the form of any suitable writing, color, etc., to indicate the polarity of the magnetic field produced by the member 254. For example, the indicator 272 may simply comprise the printed letters "N" or "S." This feature allows a user to confirm proper orientation of the device 252 relative to another device, thereby ensuring that the devices will attract each other (or repel each other, if that is desired). Other possible ways of ensuring proper orientation
20 include pre-mounting the component(s) on a delivery instrument in a selected position, or providing a mechanism that automatically orients the component in the selected position. It may also be desirable to allow the component to be removed and remounted on the delivery device if its orientation is incorrect.

Turning to Figs. 28-31, another embodiment of the invention will be described
25 and includes methods and devices for increasing the magnetic attracting force between two components. Fig. 28 shows first and second components 274, 276 adapted to be coupled to a target vessel via magnetic attraction. The first and second components 274, 276 comprise, respectively, members 278, 280 which are capable of producing a magnetic field, as well as mechanisms 282, 284 for increasing the magnetic attraction force between the components.
30 That is, when provided with the mechanisms 282, 284 and placed in proximity the components 274, 276 produce a higher magnetic force than when placed in proximity without the mechanisms.

Fig. 29 shows the components 274, 276 positioned on opposite surfaces of the

wall W of a target vessel TV and coupled thereto by magnetic force. As shown, in order to form a port that communicates with the vessel lumen L, which is partially occluded at O, the components may have openings, such as respective openings 286, 288 in components 274, 276. These openings preferably are aligned with complementary openings in the mechanisms 282, 284 to form a port extending into the lumen. The mechanisms 282, 284 enhance the magnetic attraction between the components 274, 276, thereby more securely attaching the assembly to the vessel wall W than if the mechanisms were omitted.

Referring to Figs. 30-31, the concept underlying this aspect of the invention will be described with respect to the specific embodiment of Figs. 28-29. Fig. 30 shows the first and second members 278, 280 (which may be viewed as a pair of permanent bar magnets) in relatively close proximity, the poles of the magnetic members being oriented so that the components attract each other. Fig 30 also schematically depicts the magnetic field produced by the magnetic members 278, 280. The magnetic field F1 located between the members 278, 280 is essentially uniform given the relatively large surface areas of and the small separation gap between the members. The number of lines present between the members 278, 280 is roughly indicative of the strength of field F1.

As shown, the magnetic field F2 located at the edges of the members 278, 280 fringes out, which dissipates or weakens the field F2. The field F2 fails to significantly increase the attraction force between the members 278, 280 due to its location and the fact that it is relatively weak (as it contains fewer, more spaced apart flux lines than the field F1). Put another way, the magnetic flux density or magnetic induction B (which is a measure of magnetic field strength) of field F1 is greater than the magnetic flux density of field F2. The invention provides means for utilizing the field F2 to increase the magnetic attraction force between two components. It will be noted that for sake of clarity Fig. 30 omits the portion of the magnetic field that would extend inward toward the center of each component.

Fig. 31 shows the members 278, 280 along with the mechanisms 282, 284 in fairly close proximity. The magnetic field F1 located between the members 278, 280 is essentially uniform as described above in connection with Fig. 30. As can be seen, though, the mechanisms 282, 284 alter the location and flux density of the magnetic field F2. Specifically, rather than fringing out as in Fig. 30, the field F2 is concentrated by the mechanisms 282, 284 between the components 274, 276. As such, the magnetic flux density increases, which in turn increases the attracting force between the components.

The specific manner of increasing the magnetic attraction force may vary from

that shown. The illustrated mechanisms 282, 284 are configured to alter the construction of the magnetic members 278, 280 in order to increase magnetic flux density and hence raise the attraction force produced thereby. The mechanisms 282, 284 are separate elements coupled to the members 278, 280; however, means for increasing the magnetic force may comprise an
5 integral portion of the magnetic member, a layer or coating applied to the member, etc. Further, the preferred mechanisms are channel-shaped to form an extension of the magnetic member that effectively channels the magnetic field F2 and concentrates the magnetic flux between the components 274, 276 (and more specifically, between the confronting edges of the mechanisms 282, 284). It will, however, be appreciated that this aspect of the invention
10 may be practiced using mechanisms having alternative configurations.

The mechanisms 282, 284 have a magnetic permeability higher than air in order to concentrate the magnetic flux and increase the magnetic flux density and attracting force. That is, the mechanisms provide a path of least resistance as compared to air so that the magnetic flux flows into the mechanisms rather than the air. This in effect forms a
15 magnetic circuit that captures a significant amount of the magnetic field F2 that otherwise would not contribute to the attracting force between the two components. One benefit of this aspect of the invention is that it allows a thinner magnetic member to be used for the component without sacrificing (or even increasing) magnetic field strength. In some applications, such as creating anastomoses on small vessels, it is typically desirable (e.g., for
20 thrombogenicity reasons) to minimize the amount of foreign material located within or against the vascular tissue.

The material used to form the mechanism for increasing magnetic force preferably has a high magnetic permeability μ in order to concentrate a desired amount of magnetic flux in one or more desired areas. The mechanism is preferably formed of
25 ferromagnetic material having a μ that is greater than the μ of air. More preferably, the material has a μ that is greater than 1.0, and even more preferably, significantly greater than 1.0 or as high as possible. Exemplary ranges of μ values include from about 1.0 to about 250,000, and from about 1.0 to about 1000. While ferromagnetic materials are preferably used to form the flux concentration mechanisms, other materials may be used instead. For
30 example, ferrimagnetic, paramagnetic or diamagnetic materials may be used (although the results they achieve may be inferior to those obtained using a ferromagnetic material).

Tests have shown that, depending on the size, material and separation gap of the respective components having magnetic properties, the flux concentration mechanisms of

the invention may be used to produce a magnetic attraction force that is from about 5 % to about 75 % higher than that obtained without flux concentration mechanisms. More preferable, though, is a flux concentration mechanism that increases the force from about 20 % to about 75 %. The exact amount of magnetic force used in practicing the invention, for example, to secure the components to a vessel, will depend on various factors, such as the sized of the vessel, the force limit prior to causing necrosis, etc.

It will be apparent that this feature of the invention provides ample benefits including a firm attachment to tissue via magnetic force, the ability to alter the construction of a component to customize the amount or location of flux concentration, and the ability to reduce the size of the magnetic component while maintaining sufficient magnetic force to form the anastomosis.

Figs. 32A-32B show an anastomotic component 286 in the form of an electromagnet assembly including a core 288 having an opening 290. A coil 292 is wrapped around the sidewall of the core 288 and has leads 294 running to a power source, such as battery 296 (Fig. 32B). Fig. 32B shows the component 286 after it has been placed in a protective housing 298 by suitable means, for example, a coating or structural enclosure as described above. The housing 296 is preferably formed of a strong, leak-tight biocompatible material.

Fig. 33 shows an electromagnetic component 300 for use in closing an opening, for example, an opening in tissue such as an ASD, VSD, PDA, etc. As can be seen the component 300 includes a housing 302 with at least one occlusion surface 304 adapted to seal against tissue or an anastomotic component.

Fig. 34A is an example of the component 286 coupled to an anastomotic component 286A positioned on the opposite surface of the of a target vessel TV with a lumen L. A graft vessel G is shown (in phantom) just above the component 286 and includes an anastomotic component AC oriented to magnetically attract (or be attracted to) the electromagnetic assembly of component 286. Fig. 34B shows the occluding surface 304 of component 300 being used to close, either temporarily or permanently, a magnetic port P which communicates with the lumen L of the target vessel TV.

The invention may be practiced using magnetic, mechanical, or any other force-creating means to secure a component to tissue or to another component. Fig. 35A shows two anastomotic components 304, 306 including first and second magnetic members 308, 310 enclosed in housings 312, 314. The first component 304 has a sleeve portion 316

(which in Fig. 35A is an extension of the housing 314) having an end 318 that projects beyond the second component 306. Any suitable means may be used to collapse or other manipulate the end 318 relative housing 314 of second component 306, for example, the instrument represented schematically in Fig. 35A. As shown in Fig. 35B, the instrument is moved in the direction of the arrows to collapse the end 318 and mechanically couple the securing components 304, 206. As a result, this embodiment joins the components by both magnetic and mechanical forces.

Figs. 36A-39C show another embodiment in the form of a component 320 to be coupled to tissue by a mechanical attachment portion 322. The component 320 includes a base 324 and a member 326 for producing a magnetic field. An opening 328 passes through the component 320 and is placed in communication with a target vessel, for example, a coronary or peripheral artery. Figs. 36A-36B and 37A-37C show the component 320 in a low profile or collapsed configuration for delivery. The illustrated attachment portion 322 includes a plurality of arms 330 adapted to engage tissue of the target vessel wall, which results in the vessel wall being sandwiched between the ends 332 of the arms 330 and the base 324. The component 320 may comprise separate members, as in the illustrated embodiment, or it may comprise an integral structure with or without a magnetic portion.

Figs. 38A-38B and 39A-39C show the component 320 in a raised profile or expanded configuration corresponding to its deployed, tissue-engaging position. Fig. 39B shows (in phantom) tissue T engaged by the expanded arm 332. These Figures show, however, an optional feature of this embodiment, namely, a biocompatible layer G adapted to be placed in contact with the tissue. Exemplary uses for such as layer, which may be formed of any suitable material, include sealing the vessel opening and promoting tissue ingrowth at the site. This embodiment of the invention uses mechanical force to couple a component to the tissue but forms a magnetic port (via member 326) that may be anastomosed to another component having the same or a different construction. It will be recognized that the component 320, rather than presenting a magnetic port for docking a vessel, could present an alternative structure for attaching a graft, such as a stent, staples or fasteners, adhesive, etc.

Figs. 40A-40C shows an exemplary use of the device illustrated in Figs. 36A-39C. A delivery device 334 is schematically shown and includes a tip 336 which is preferably configured to incise and dilate tissue. The tip 336 may be mounted on a shaft 338 and has a recess that receives the ends 332 of the arms 330 (Fig. 40A) and retains them in their collapsed configuration. The delivery device 334 also has an end 340 for contacting the

magnetic member 326 of the component 320 to prevent movement of the arms 330 relative to the delivery device.

Fig. 40A shows the device 334 after the tip 336 has cut through tissue of a vessel wall W and the component has been properly positioned against the surface of the wall.

5 Fig. 40B shows the device 334 after the shaft 338 has been moved distally to release the ends 332 of component arms 330 and allow them to expand into contact with the tissue T. Next, as shown in Fig. 40C, the delivery device 334 with shaft 338 is removed proximally through the opening 328 of component 320.

It will of course be appreciated that this embodiment of the invention may take
10 many constructions other than those specifically illustrated herein. For example, rather than having individual arms 330 which engage the tissue T, a continuous or semi-continuous surface could be used, the surface being planar, concave-convex, etc.

Figs. 41A-41C show a delivery device constructed according to yet another embodiment of the invention. The delivery device 342 includes a support portion 344 and a
15 retaining portion or mechanism 346 for retaining a securing component SC on the device. The illustrated retaining portion 346 is carried by a shaft 348 and engages a flange 350 formed on (or attached to) the securing component SC around its opening 352. The flanged securing component SC is preferably magnetic and may be constructed as described above regarding previous embodiments (e.g., Figs. 19A-19C). Fig. 41A shows the delivery device
20 342 in a first position in which the retaining portion 346 is in its first position to retain the securing component SC. It will be noted that the device 342 may also be used to deliver a non-flanged securing component(s).

Fig. 41B shows the delivery device 342 after the retaining portion 346 has been moved out of the first position to release the securing component 342. In this
25 embodiment the retaining portion is rotated 90° from the first position, although other motions may be used to release and engage the securing component. Fig. 41C shows the delivery device 342 after it has been withdrawn proximally through the opening 352 in the securing component 342. Fig. 41C also shows the particular construction of the support portion 344 of device 342. A step 354 is formed to receive the opening 352 of the securing
30 component 342. The step 354 helps align the securing component and aids in even delivery to the tissue surface.

Figs. 42A-42C show a delivery device 356 constructed according yet another embodiment of the invention. The device 356 includes a body 358 which to some extent acts

as a support portion for first and second components 360, 362. A first retaining portion or mechanism 364 is movable relative the body 358 and engages the first component 360 to retain it in place prior to and during delivery. A second retaining portion or mechanism 366 is also movable and engages the second component 362 to retain it in place. A shaft 368 supports the first retaining portion 364, and the body 358 has a notch 370 which facilitates introducing the components into a vessel lumen, as described below.

Fig. 42B shows the device 356 after the second retaining portion 366 has been moved toward first component 360 to drive the second component 362 to its desired position, for example, against an opposite surface of the vessel wall. Fig. 42C shows the device 356 after the first retaining portion 364 has been moved distally relative to the body 358 of the device. The portion 364 is wedge-shaped and this motion moves the portion 364 out of contact with the first component 360, thereby releasing it from the device. Magnetic attraction maintains the two components 360, 362 in place.

Figs. 43A-43C show the delivery device 356 being used to couple the first and second components 360, 362 to a vessel wall W. As shown in Fig. 43A, the notch 370 can be used to guide the first component 360 through an incision in the wall W. It should be noted now that another aspect of this embodiment provides an offset structure for easier introduction of the leading end of a component. As can be seen in Fig. 43A, this feature allows the longer component 360 to be introduced through a shorter incision. The term offset means that the body 358, i.e., the delivery end of the device 356, extends laterally in one direction to give the device an asymmetrical configuration. For example, in the illustrated embodiment the body 358 extends to one side and defines the notch 370, but does not extend laterally in the opposite direction. Put another way, the delivery end of the device 356 is offset with respect to a longitudinal axis of the device.

Fig. 43B show the first component 360 passed through the incision and the second component 362 being lowered to a position that achieves the desired amount of magnetic attracting force. Fig. 43C shows the resulting position of the two components with their openings generally aligned with the incision in the wall W.

As mentioned above with respect to Fig. 5, the invention may be practiced using flexible components that are capable of producing a magnetic field. Fig. 44 shows another embodiment comprising a component 374 in the form of a foldable sheet being collapsed, for example, in order to deliver the component percutaneously. Figs. 45A-45B show, respectively, expanded and collapsed orientations of a component 376 constructed

according to another embodiment. Figs. 46A-46B show, respectively, components 378, 380 having magnets 382 disposed partially therein so as to allow at least partial collapsing of the components in accordance with yet another embodiment.

Fig. 46C shows a component 384 constructed according to another
5 embodiment in its expanded state. A frame 386 supports a web or body 388 and is capable of producing a magnetic field while being collapsible for easier delivery. The web 388 may be used to occlude an opening. Fig. 46D shows a collapsible component 390 that may be used to form a magnetic port or an anastomosis. The component 390 preferably comprises a
10 magnetic core covered by a superelastic or shape memory housing and has ends 392 that permit the component to be delivered in a straight, low-profile configuration. Fig. 46E shows an exemplary catheter C retaining the component 390 in a low-profile orientation.

Figs. 47A-47C show yet another embodiment of the invention that provides a device 394 for closing an opening in tissue, such as any of the cardiovascular defects mentioned above. The device 394 could be used in other applications as well. In Fig. 47A a
15 sheath or catheter 396 houses a pair of magnetic components 398, 400 on a shaft 402. The components 398, 400 may take any of the previously described constructions and are configured to attract each other across a body of tissue with an opening to be closed. Fig. 47B shows the device 394 after relative movement has been imparted to the sheath 396 and the components 398, 400. The component 398 is out of the sheath 396 and fully expanded
20 while the component 400 is partially out of the sheath and expanded. Fig. 47C shows the device 394 with the component 398 exploded from the shaft 402. The shaft 402 and component 398 have mating magnetic and/or mechanical interlocking means indicated at 404, such means securely holding the component 398 during delivery and then releasing it preferably via remote actuation upon reaching the target site.

25 Figs. 48A-48C show an exemplary application of the embodiment illustrated in Figs. 47A-47C wherein the device 394 is used to close a ventricular septal defect VSD in the septum S between the right and left ventricles RV, LV. Fig. 48 shows the device 394 introduced percutaneously into the right ventricle RV and the component 398 located and expanded in the left ventricle LV. The component 398 is forced against the septum S and the
30 other component 400 is expanded as shown in Fig. 48B. Once expanded, component 400 is forced against the septum S (e.g., by using the sheath 396), attracts the component 398 to close the defect, and the device 394 is removed (Fig 48C).

The preferred embodiments of the invention are described above in detail for

the purpose of setting forth a complete disclosure and for sake of explanation and clarity. It will be readily understood that the scope of the invention defined by the appended claims will encompass numerous changes and modifications.

WHAT IS CLAIMED IS:

- 1 1. A device for forming a magnetic port in a hollow body having a lumen,
2 the device comprising:
3 a component capable of producing a magnetic field and having an opening
4 configured to be placed in communication with the lumen of the hollow body; and
5 a housing disposed on an exterior of the component, the housing providing a
6 substantially sealed enclosure containing the component;
7 wherein the housing is formed of a biocompatible material adapted to be
8 implanted in a patient.
- 1 2. The device of claim 1, wherein the housing provides a hermetically-
2 sealed enclosure containing the component.
- 1 3. The device of claim 1, wherein the housing comprises a plurality of
2 members cooperating to provide the sealed enclosure containing the component.
- 1 4. The device of claim 3, wherein one housing member is a dish and
2 another housing member is configured to close the dish and seal the component therein.
- 1 5. The device of claim 1, wherein the housing comprises a metallic
2 material.
- 1 6. The device of claim 5, wherein the housing comprises a plurality of
2 titanium members joined by welding.
- 1 7. The device of claim 1, wherein the housing includes an indicator of the
2 polarity of the magnetic field produced by the component.
- 1 8. A device adapted to be coupled to tissue using magnetic force, the
2 device comprising:
3 a first securing component capable of producing a magnetic field, the first
4 securing component being adapted to attract a second securing component that is capable of
5 producing a magnetic field; and

6 a magnetic force-increasing mechanism for increasing the magnetic force
7 attracting the first and second securing components when the first securing component is
8 positioned in proximity to the second securing component.

1 9. The device of claim 8, wherein the magnetic force-increasing
2 mechanism has a magnetic permeability greater than 1.0.

1 10. The device of claim 9, wherein the magnetic force-increasing
2 mechanism has a magnetic permeability greater than 100.

1 11. The device of claim 9, wherein the magnetic force-increasing
2 mechanism is configured to alter the magnetic flux density of the first securing component

1 12. The device of claim 11, wherein the magnetic force-increasing
2 mechanism is configured to concentrate magnetic flux in a desired location.

1 13. The device of claim 12, wherein the first securing component is plate-
2 shaped and the flux concentration mechanism comprises a separate channel-shaped strip of
3 material disposed along and forming an extension of at least one edge of the first securing
4 component.

1 14. The device of claim 8, wherein when the first securing component is
2 positioned a given distance from the second securing component the magnetic force attracting
3 the components is from about 5 % to about 75 % higher than the magnetic force attracting the
4 components without the flux concentration mechanism.

1 15. The device of claim 14, wherein when the first securing component is
2 positioned a given distance from the second securing component the magnetic force attracting
3 the components is at least 20 % higher than the magnetic force attracting the components
4 without the flux concentration mechanism.

1 16. The device of claim 14, further comprising a second securing
2 component sized and configured generally complementarily to the first securing component,
3 wherein the second securing component is capable of producing a magnetic field that attracts
4 the first securing component and includes a flux concentration mechanism.

1 17. The device of claim 16, wherein the first securing component includes
2 a portion for mechanically engaging the second securing component device to couple the
3 securing components mechanically and by magnetic force.

1 18. A device adapted to be coupled to a blood vessel having a lumen so as
2 to produce a magnetic field adjacent the blood vessel, the device comprising:
3 at least one securing component sized and configured to be secured to a blood
4 vessel having a lumen, the one securing component being capable of producing a magnetic
5 field;

6 wherein the one securing component has an indicator that indicates the polarity
7 of the magnetic field to a user carrying out a procedure on the blood vessel.

1 19. The device of claim 18, wherein the indicator comprises a visual
2 marker on the one securing component that indicates a selected polarity of the magnetic field.

1 20. The device of claim 18, further comprising a delivery device
2 supporting the one securing component, and wherein the indicator comprises a predetermined
3 portion of the one securing component that is aligned with the delivery device to ensure that
4 the one securing component is located with the selected polarity oriented in a desired
5 position.

1 21. The device of claim 18, further comprising a second securing
2 component that produces a magnetic field and is attracted to the one securing component,
3 wherein the second component also has an indicator that indicates the polarity of the magnetic
4 field produced by the second component to ensure that the securing components are
5 positioned to ensure their attraction.

1 22. The device of claim 21, wherein the one securing component is
2 adapted to be coupled to a target vessel to form a magnetic port that communicates with the
3 vessel lumen, and the second securing component is adapted to be coupled to the one
4 securing component to form a vascular anastomosis using magnetic force.

1 23. The device of claim 18, wherein the one securing component
2 comprises an electromagnet coupled to a power source.

1 24. The device of 23, wherein the electromagnet is contained in a
2 protective housing.

1 25. A device for forming a port in a first hollow body having a lumen, the
2 device comprising:

3 a securing component having an opening adapted to be placed in
4 communication with an opening in the wall of the first hollow body so as to be in
5 communication with the lumen of the first hollow body; and

6 a mechanical attachment portion configured to secure the component to the
7 first hollow body in a desired position;

8 wherein the securing component is configured to produce a magnetic field
9 adjacent the opening in the first hollow body.

1 26. The device of claim 25, wherein the mechanical attachment portion
2 comprises a structure that is at least partially collapsible for delivery through the opening in
3 the wall of the first hollow body and then expandable to engage the wall of the first hollow
4 body.

1 27. The device of claim 26, wherein the collapsible structure comprises a
2 tube with self-expanding arms that are generally coplanar for contacting the wall of the first
3 hollow body when the arms are expanded.

1 28. The device of claim 27, wherein the tube defines an opening that is
2 aligned with the opening in the securing component.

1 29. The device of claim 25, wherein the securing component has a
2 laminated structure and includes a layer of biocompatible material to enhance sealing of the
3 opening in the wall of the first hollow body.

1 30. The device of claim 29, wherein the attachment portion is secured to a
2 separate member formed of a material capable of producing a magnetic field.

1 31. The device of claim 25, wherein the mechanical attachment portion is
2 adapted to provide the sole attachment between the securing component and the first hollow
3 body.

1 32. The device of claim 25, wherein the opening in the securing
2 component has a shape selected from the group consisting of circular, elliptical, racetrack,
3 football and canoe-shaped configurations.

1 33. A delivery device in combination with a component for forming an
2 anastomosis, the combination comprising:
3 at least one component having an opening adapted to be placed in
4 communication with a lumen of a vessel in a patient's body, the component being capable of
5 producing a magnetic field; and

6 a delivery device including a support portion supporting the component and a
7 retaining portion that is movable with respect to the support portion, wherein the retaining
8 portion is placed in a first position to retain the component and is moved from the first
9 position to release the component;

10 wherein the retaining portion is movable with respect to the support portion in
11 a direction selected from the group consisting of axial and rotary directions.

1 34. The combination of claim 33, further comprising a portion for
2 supporting a second component, and wherein the support portion and the retaining portion of
3 the delivery device are configured to contact different areas of the component.

1 35. The combination of claim 33, wherein the retaining portion comprises
2 a rotatable rod with a portion contacting the component.

1 36. The combination of claim 33, wherein the retaining portion comprises
2 a wedge slidably disposed with respect to the support portion, the wedge contacting the
3 component when the retaining portion is in the first position.

1 37. The combination of claim 33, wherein the delivery device has a
2 delivery end adapted to support at least one component, and the delivery end is laterally offset
3 with respect to a longitudinal axis of the delivery device.

1 38. The combination of claim 37, wherein the delivery end has a notch
2 adapted to receive tissue as the device is being used to introduce the component into the
3 lumen of a vessel.

1 39. The combination of claim 33, wherein the component comprises a
2 magnetic material and the delivery device comprises a ferromagnetic material.

1 40. A method for increasing the magnetic force between first and second
2 anastomotic securing components, the method comprising steps of:

3 (a) providing first and second anastomotic securing components each of
4 which is capable of producing a magnetic field, the first and second securing components
5 having respective openings adapted to be placed in communication with each other; and

6 (b) increasing the magnetic force between the first and second securing
7 components by concentrating magnetic flux between the securing components.

1 41. The method of claim 40, wherein step (b) is performed by altering the
2 construction of at least one of the first and second securing components to concentrate
3 magnetic flux between the components.

1 42. The method of claim 40, wherein step (b) is performed by providing
2 the first and second securing components with respective flux concentration mechanisms that
3 are formed of a material having a higher magnetic permeability than air.

1 43. A method for coupling a securing component to a target vessel in order
2 to form a magnetic port communicating with a lumen of the target vessel, the method
3 comprising steps of:

4 (a) providing at least one securing component capable of producing a
5 magnetic field and having an opening adapted to be placed in communication with the lumen
6 of the target vessel;

7 (b) coupling the one securing component to the target vessel with the opening
8 in the one securing component communicating with the target vessel lumen; and

9 (c) prior to completing step (b) confirming the orientation of the polarity of
10 the magnetic field produced by the one securing component.

1 44. The method of claim 43, wherein step (c) is performed by pre-loading
2 the securing component on a delivery device in a predetermined position that properly orients
3 the polarity of the magnetic field.

1 45. The method of claim 44, wherein the delivery device removably
2 supports the one securing component to allow removal and reloading of the component if the
3 polarity is improperly oriented.

1 46. The method of claim 43, wherein step (a) is performed by providing
2 first and second anastomotic securing components each of which is capable of producing a
3 magnetic field, step (b) is performed by positioning the securing components against opposite
4 surfaces of the wall of the target vessel, and step (c) is performed by checking a visual marker
5 carried on at least one of the securing components.

1 47. A method for forming a magnetic port in a first hollow body located
2 within a patient, the first hollow body having a lumen, the method comprising steps of:

3 (a) forming an opening in a wall of the first hollow body, the opening
4 extending into the lumen of the first hollow body;

5 (b) providing a first securing component capable of producing a magnetic
6 field and having an opening adapted to be placed in communication with the opening in the
7 wall of the first hollow body; and

8 (c) coupling the first securing component to the first hollow body by a
9 mechanical attachment to form a magnetic port in the first hollow body.

1 48. The method of claim 47, wherein the first securing component is
2 coupled to the first hollow body solely by a mechanical attachment.

1 49. The method of claim 47, further comprising the steps of providing a
2 second securing component capable of producing or being attracted by a magnetic field,
3 joining the second securing component to a second hollow body, and coupling the second
4 securing component to the magnetic port created according to step (c) to form an end-to-side
5 anastomosis between the first and second hollow bodies.

FIG. 1

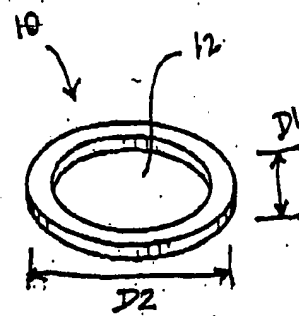


FIG. 2

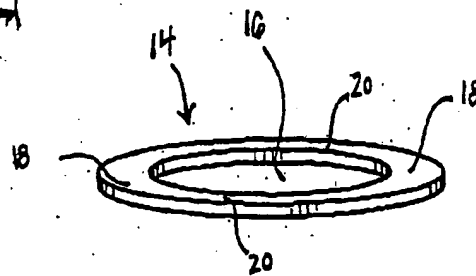


FIG. 3

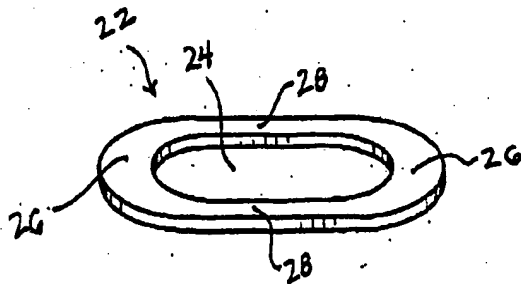


FIG. 4

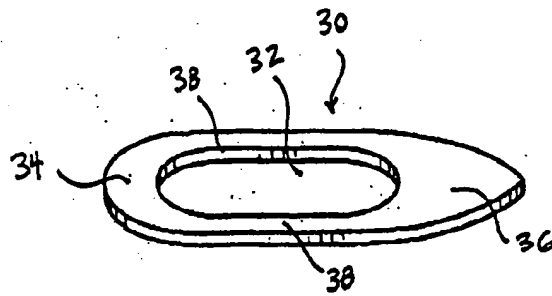
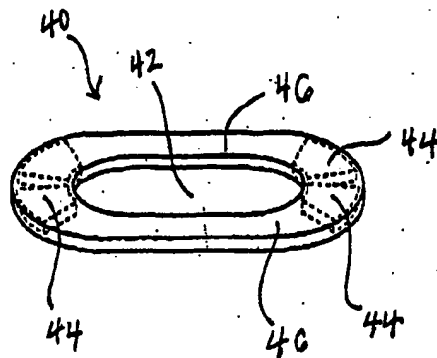
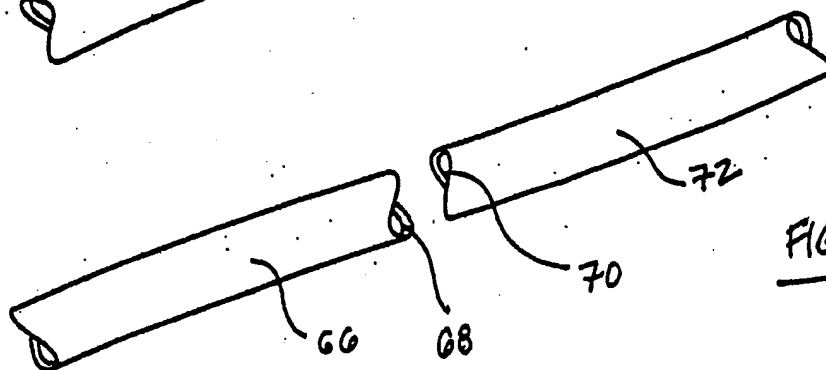
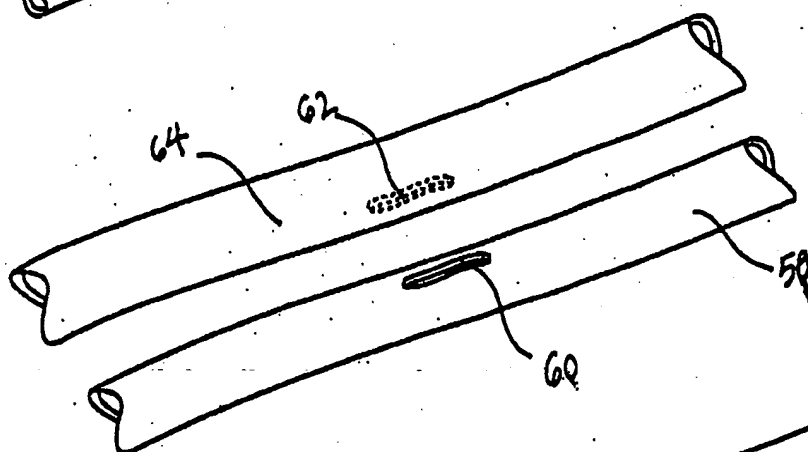
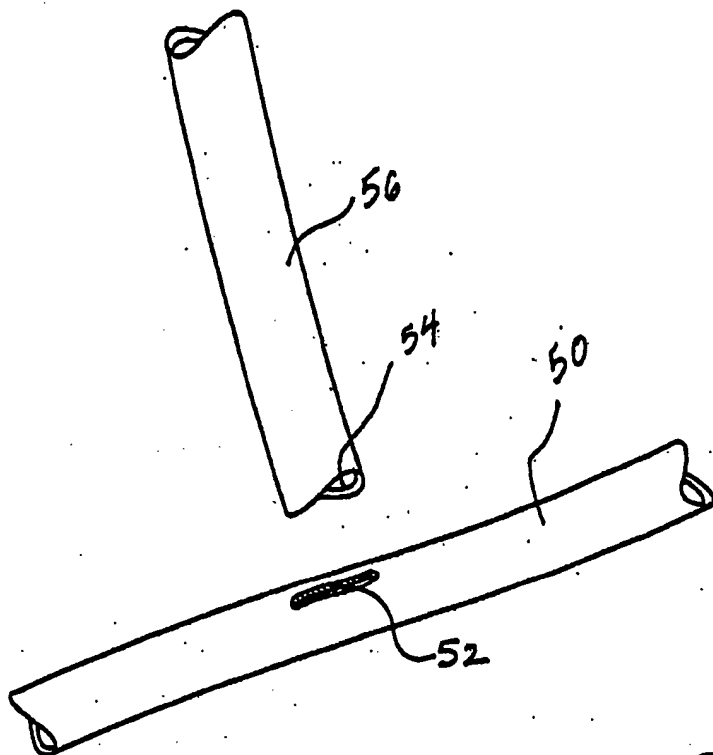
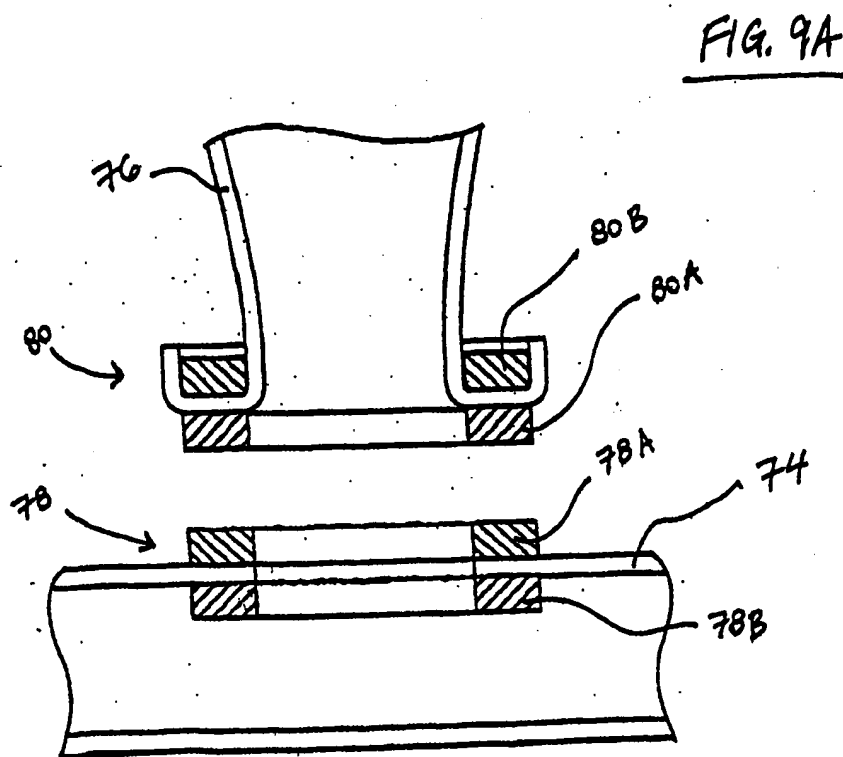
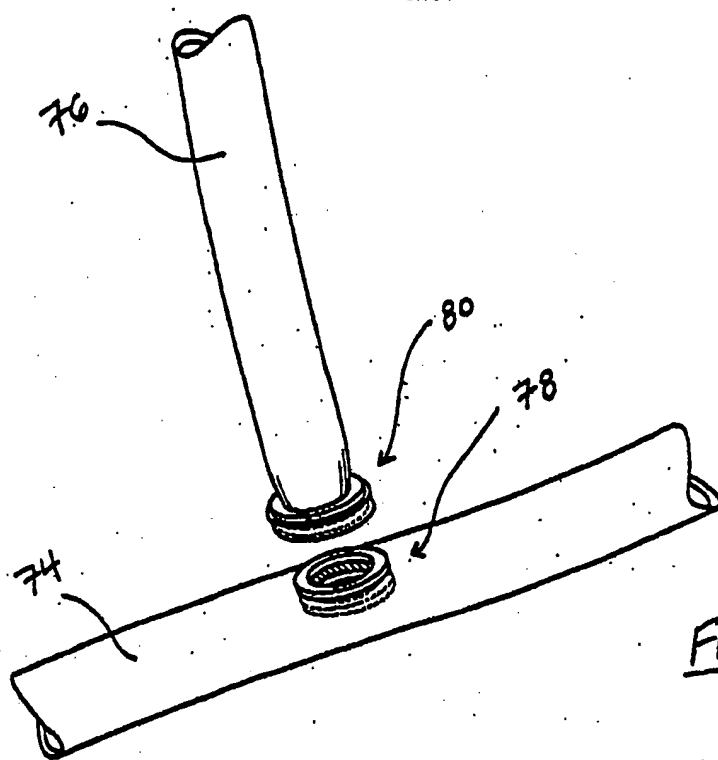


FIG. 5







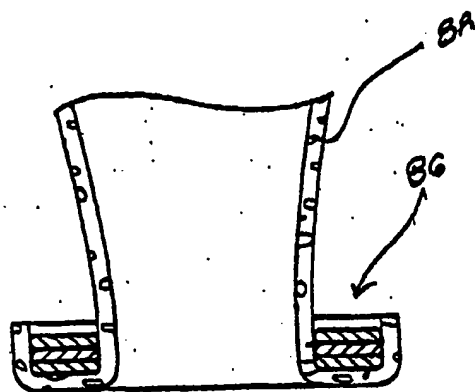


FIG. 10A

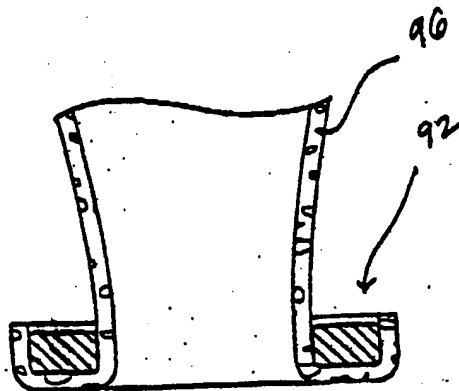
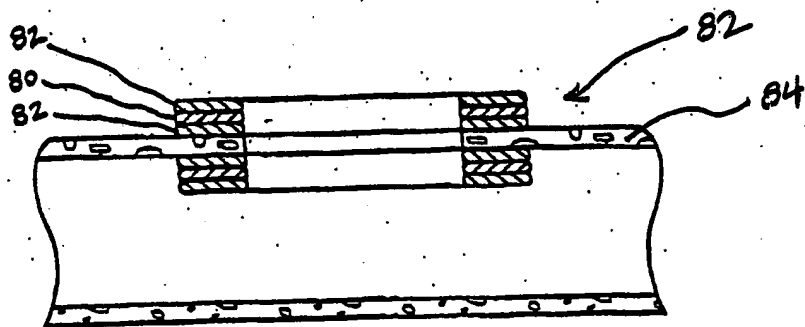
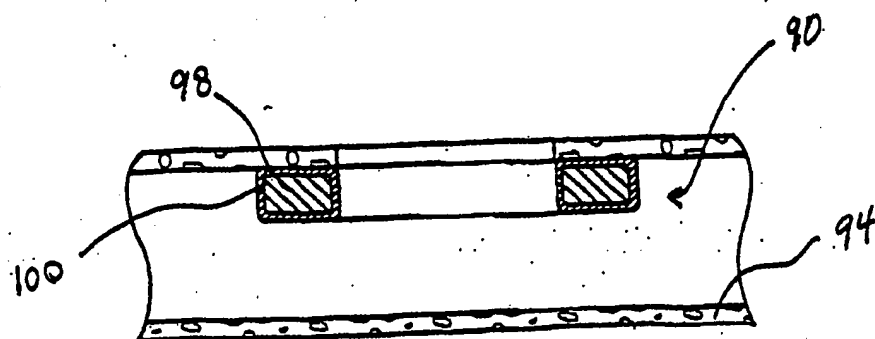


FIG. 10B



5/137

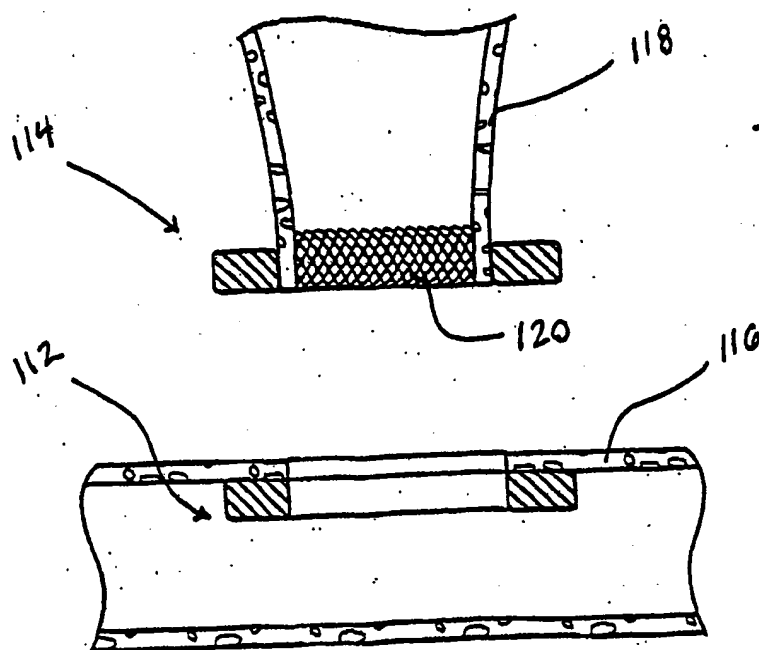
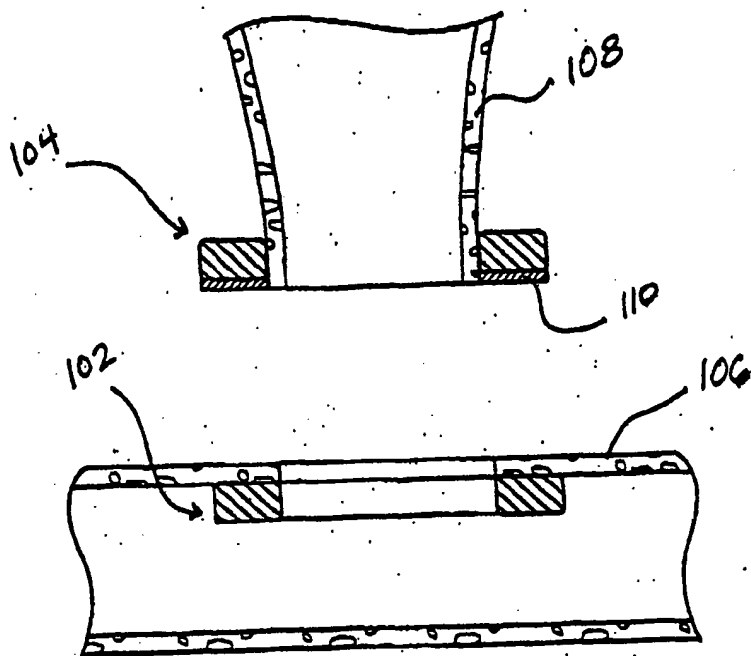


FIG. 11A

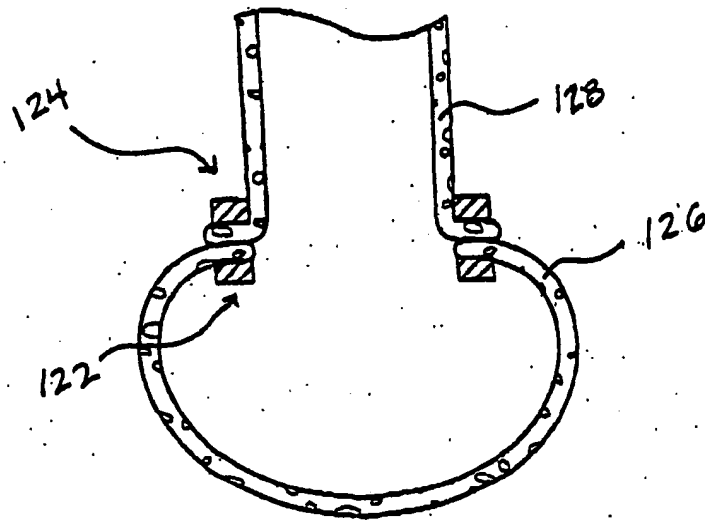


FIG. 11B

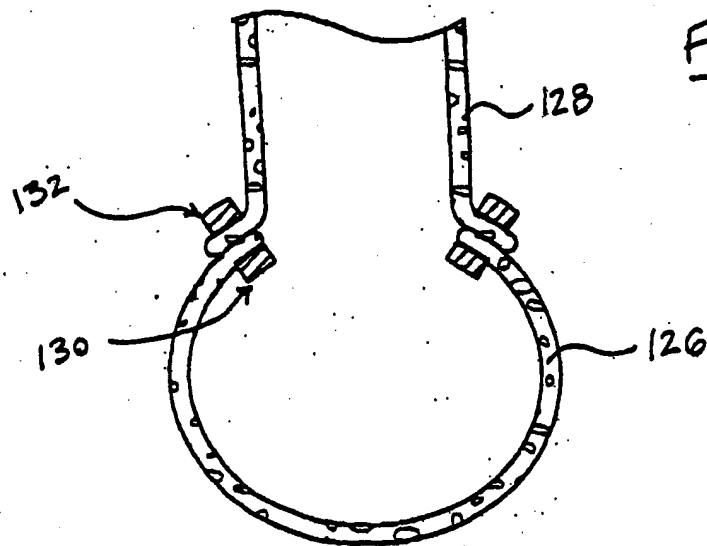


FIG. 12

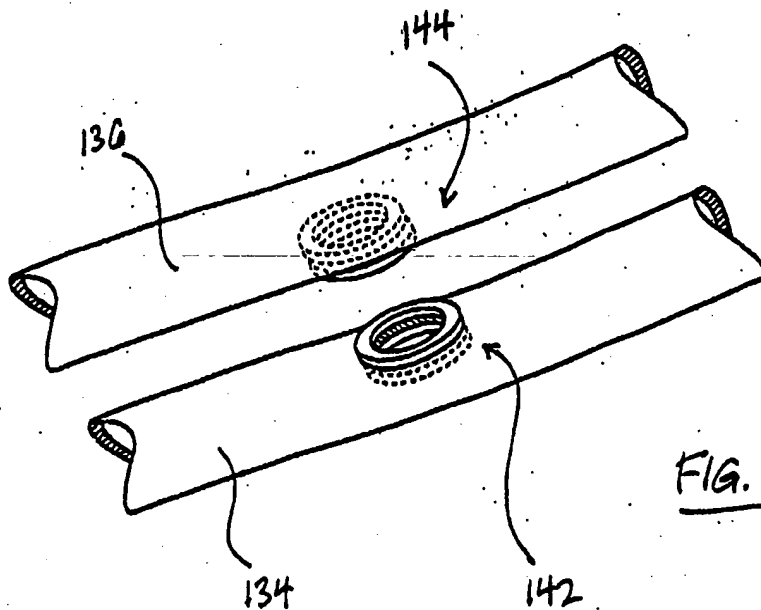
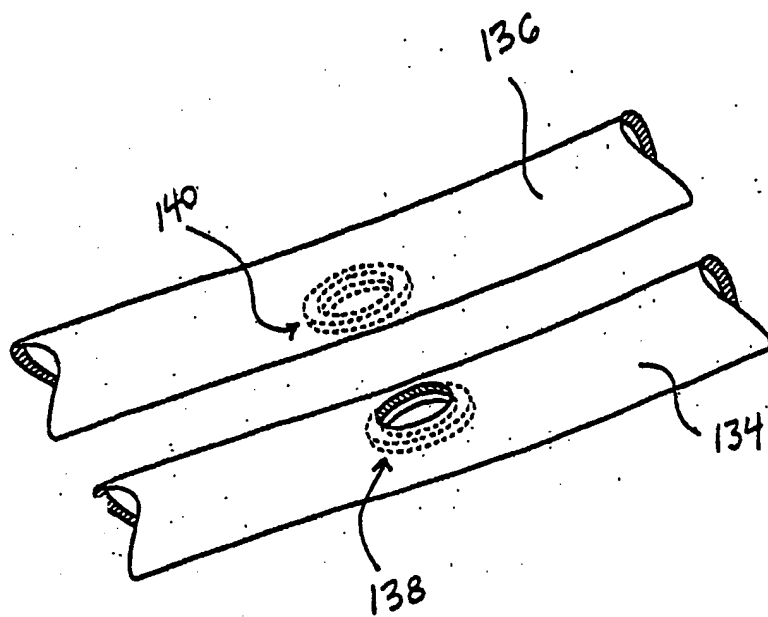


FIG. 13

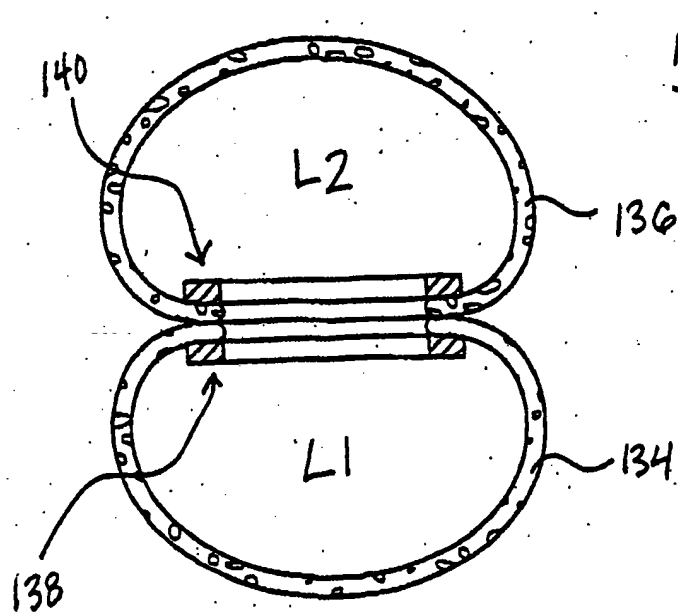
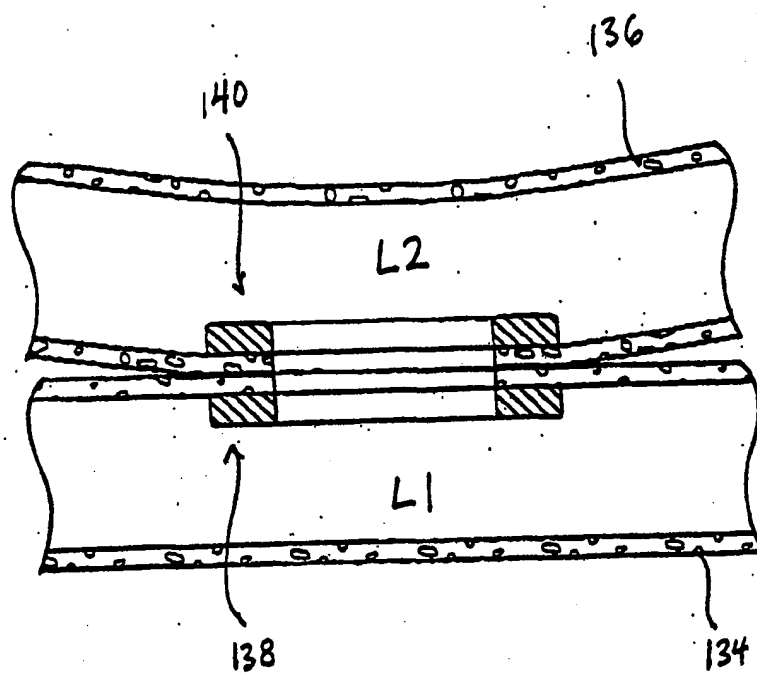


FIG. 15

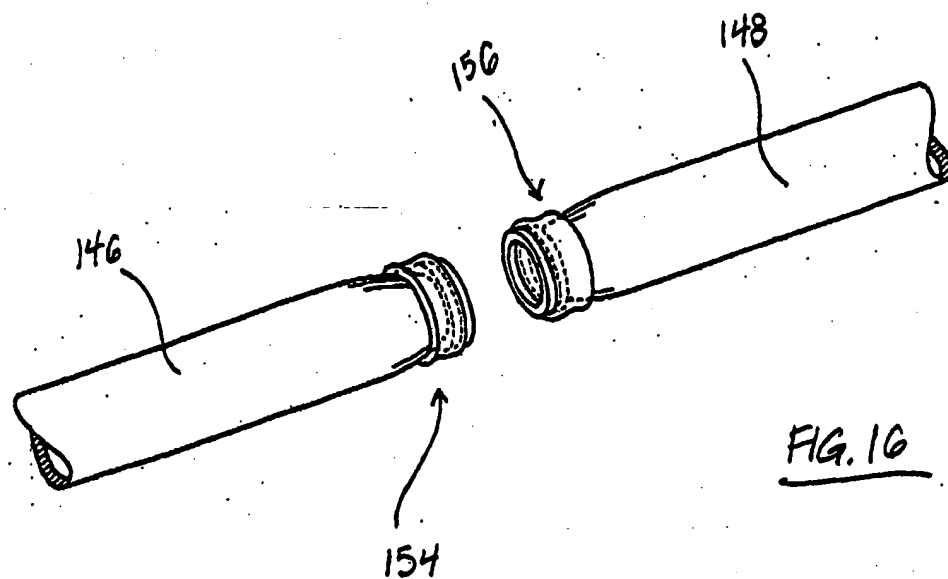
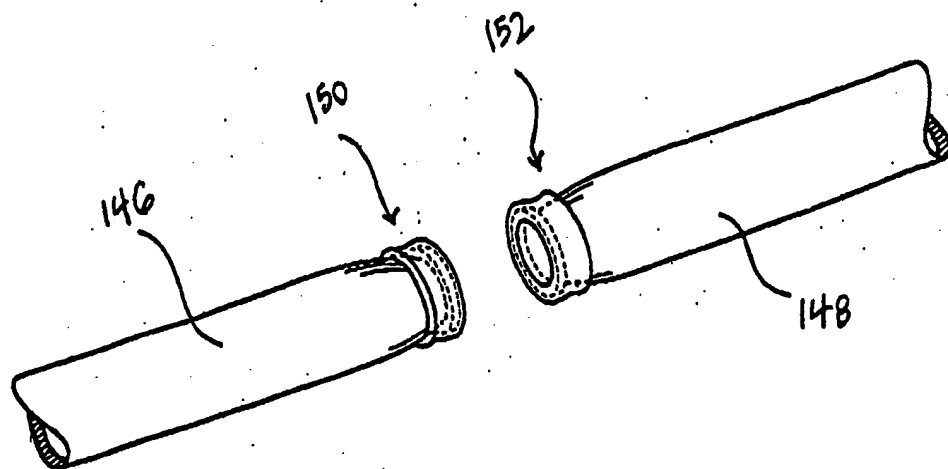


FIG. 16

FIG. 17A

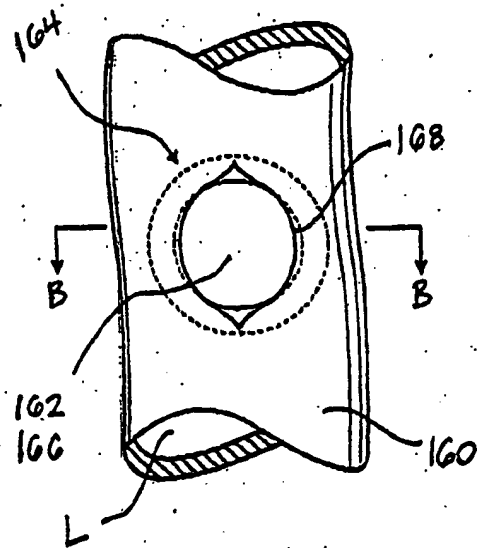


FIG. 17B

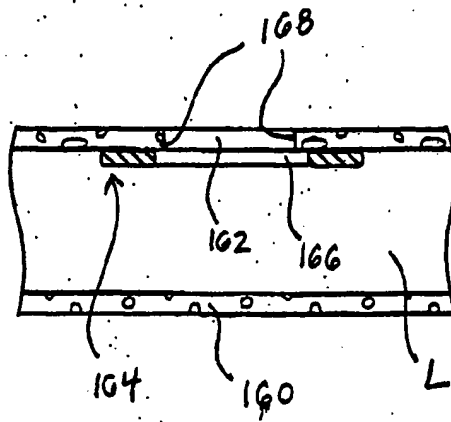


FIG. 18A

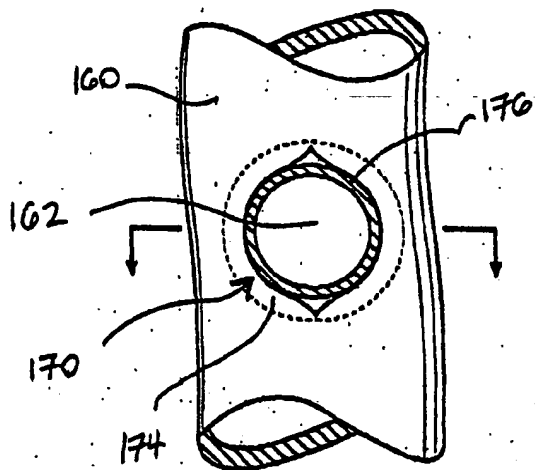


FIG. 18B

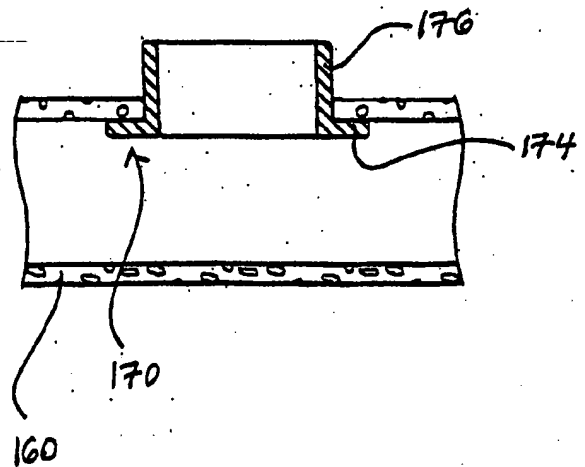
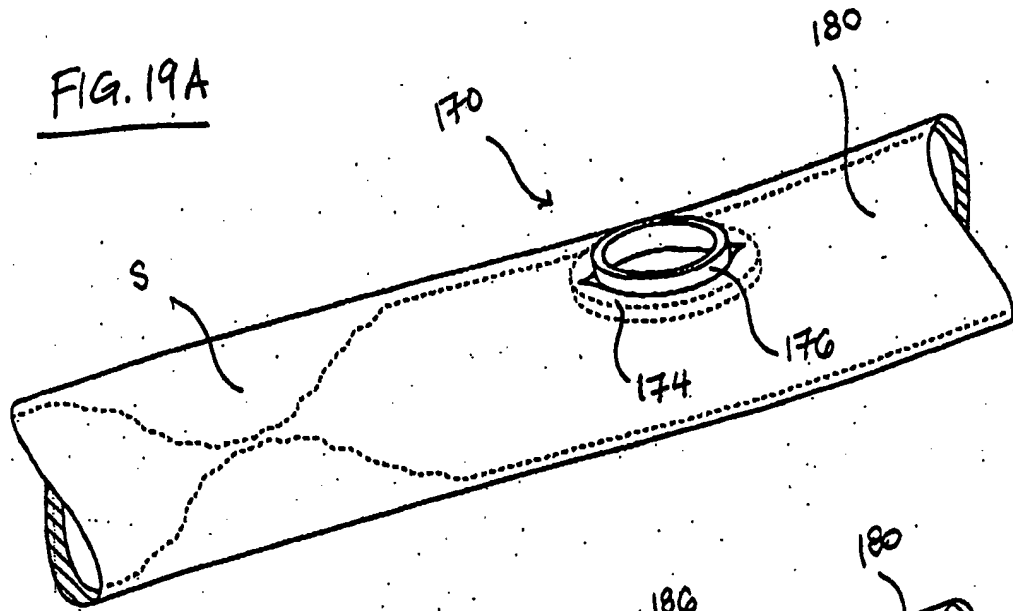
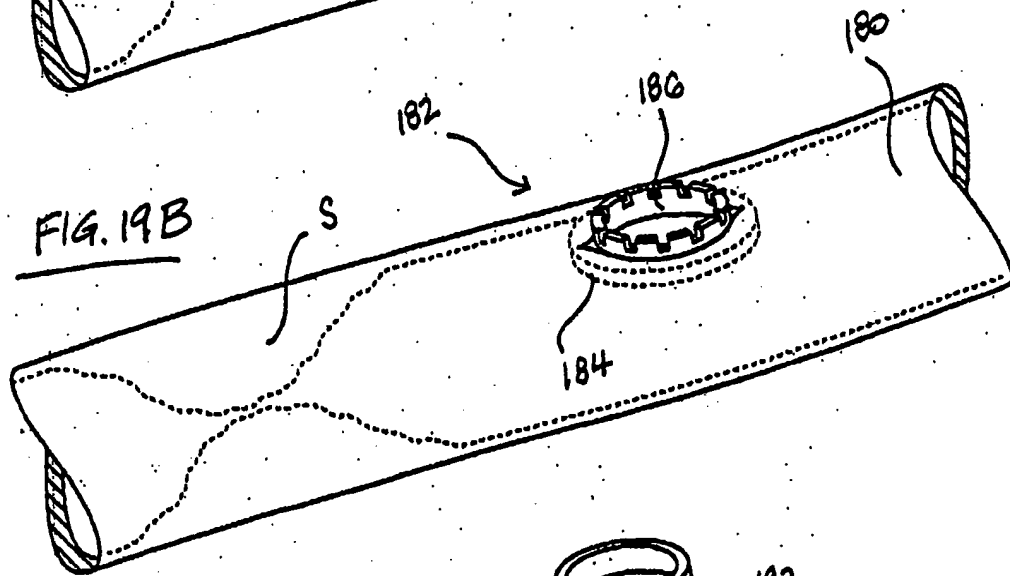
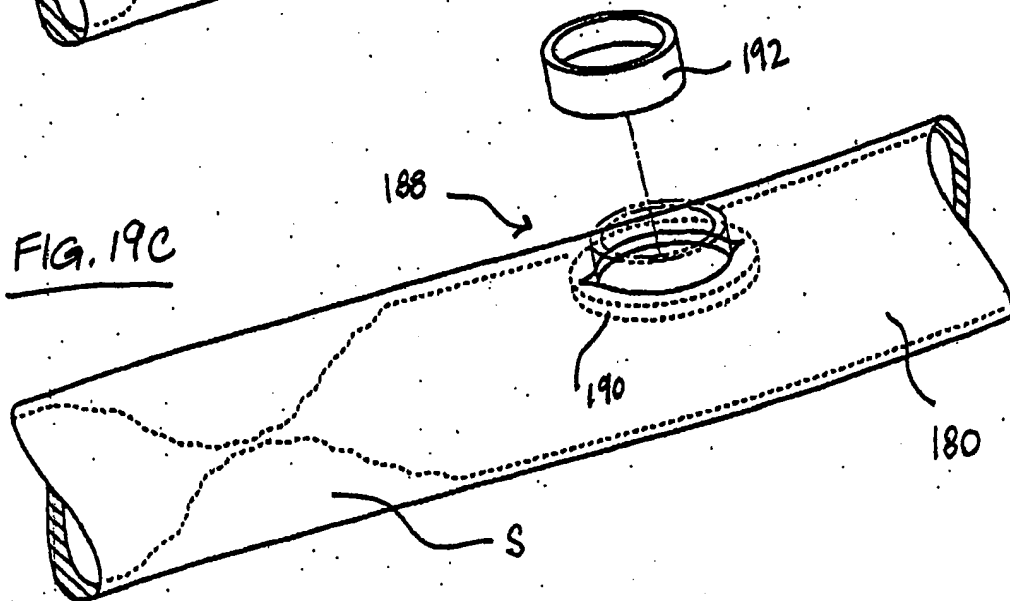


FIG. 19AFIG. 19BFIG. 19C

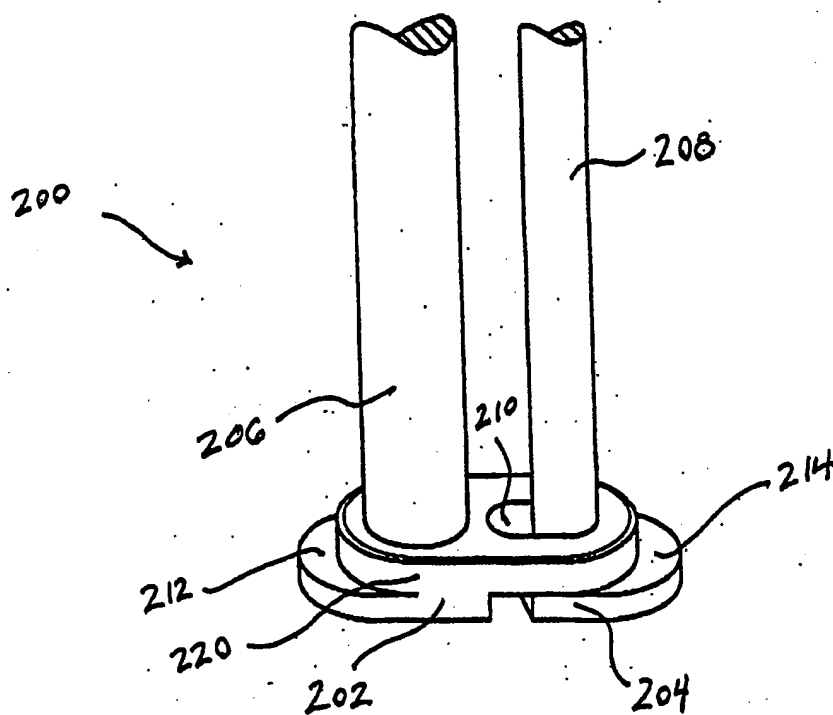


FIG. 20A

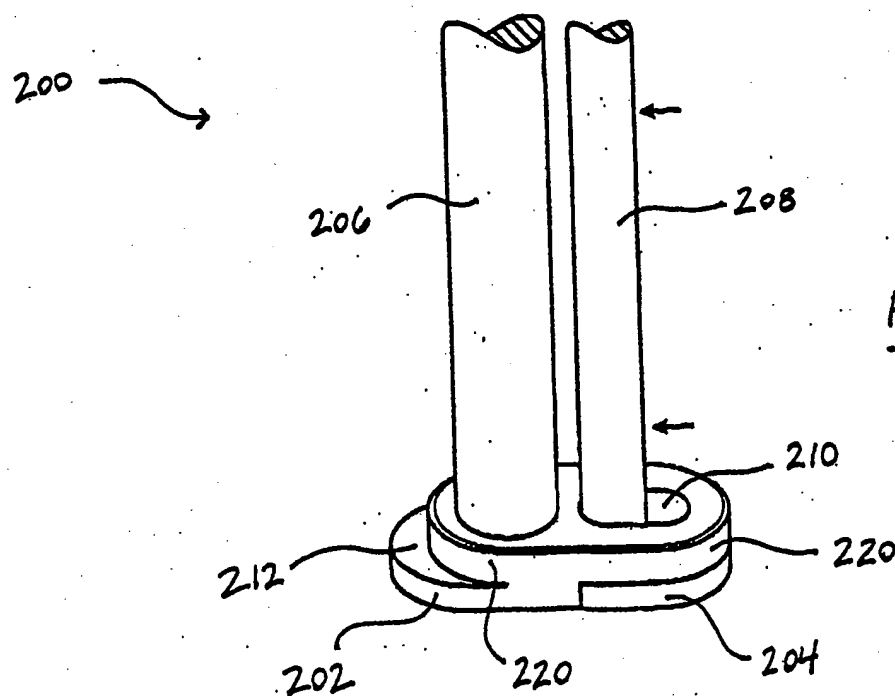


FIG. 20B

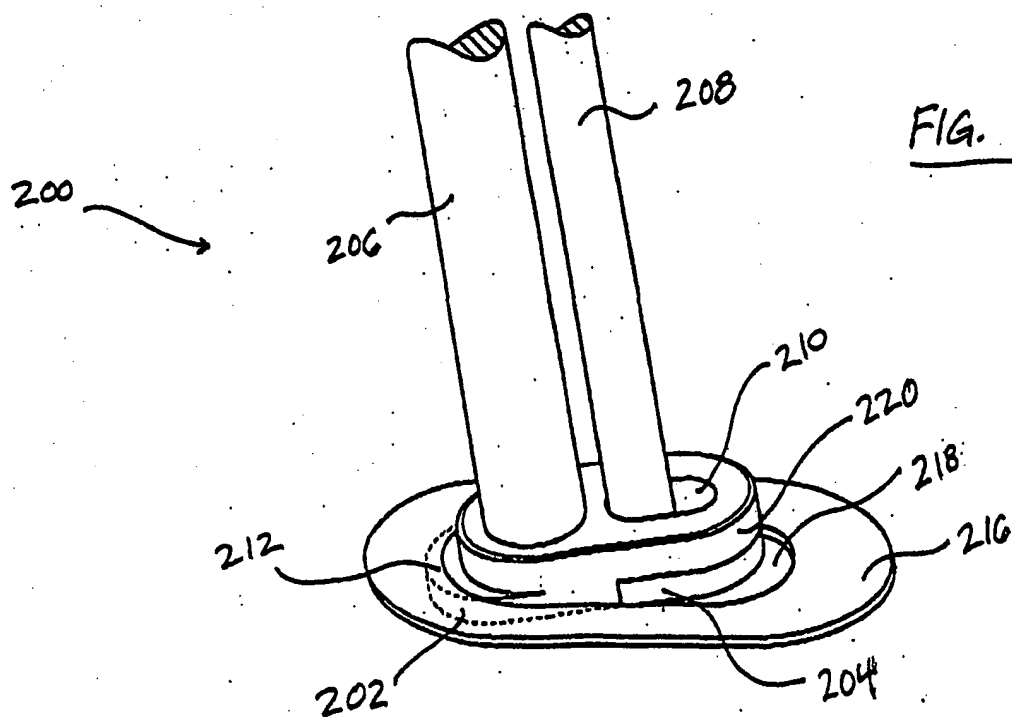
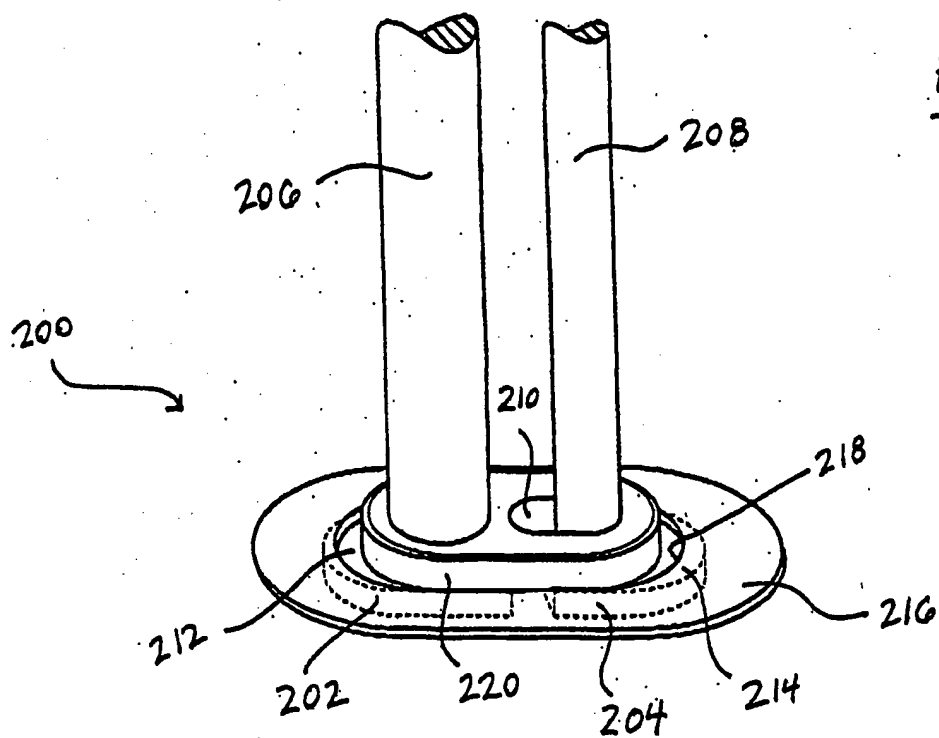


FIG. 22A

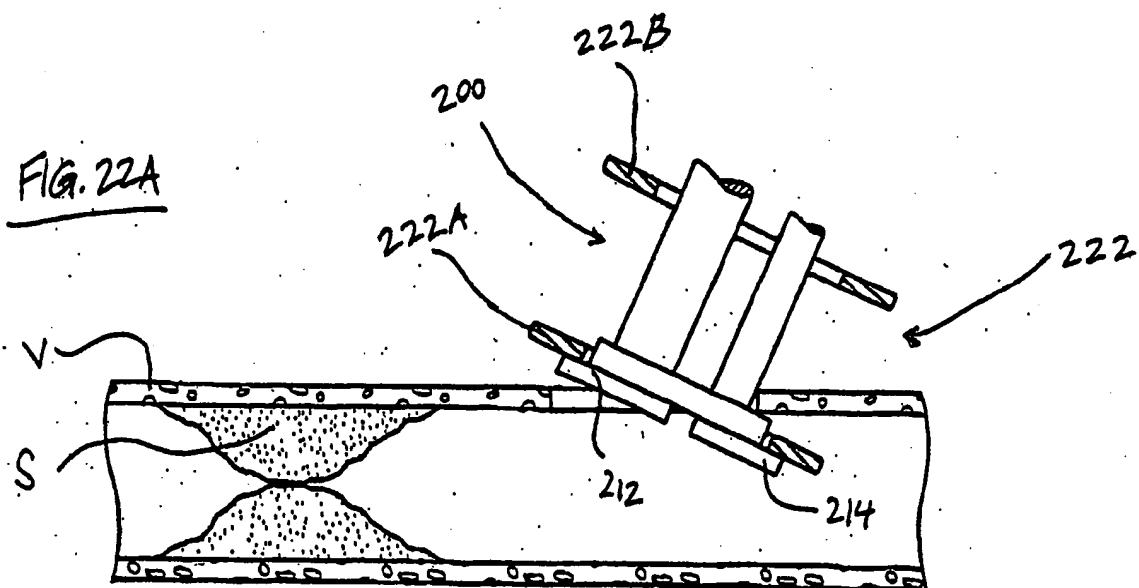


FIG. 22B

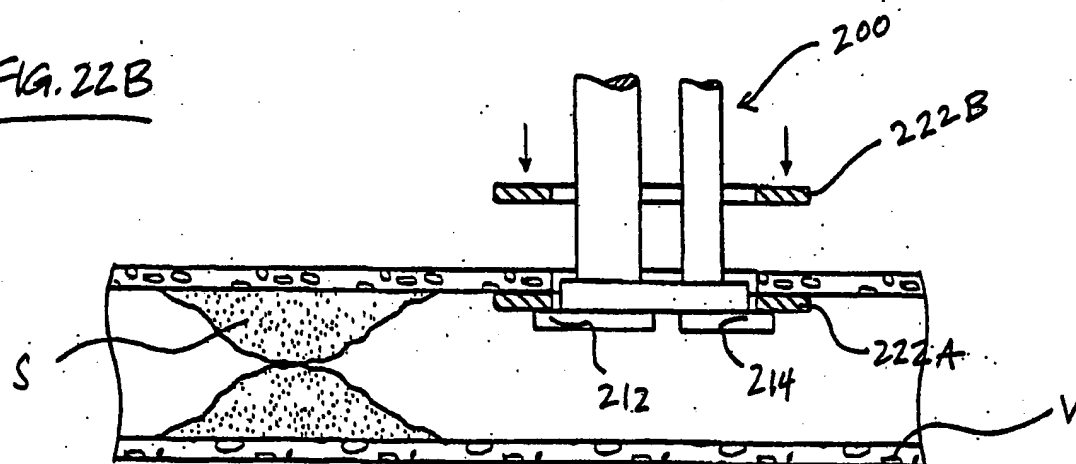


FIG. 22C

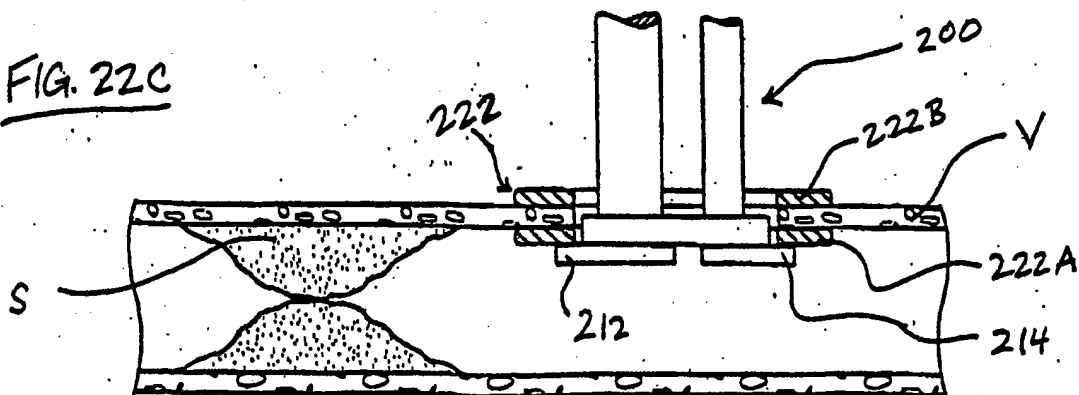


FIG. 22D

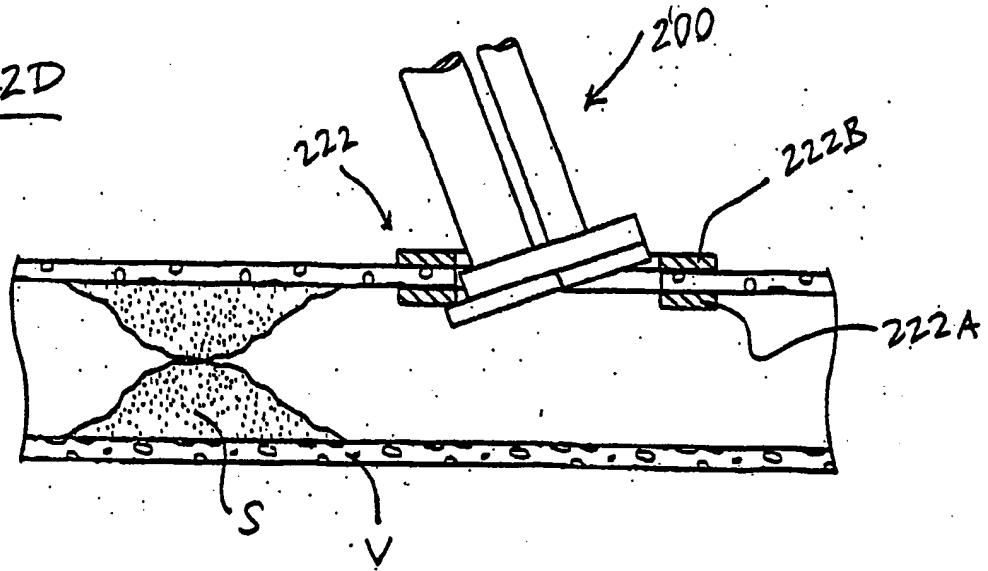


FIG. 22E

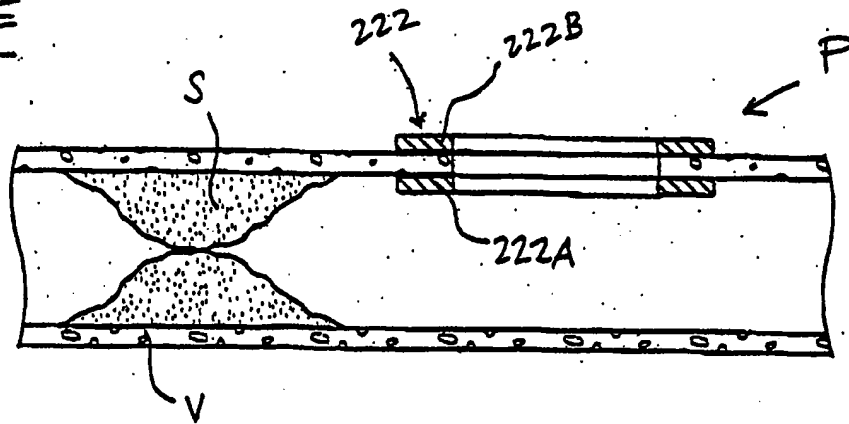
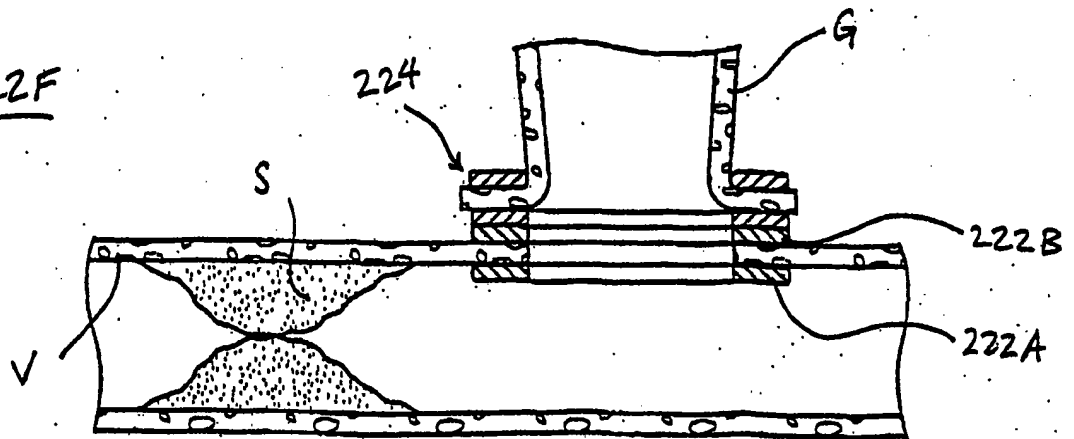


FIG. 22F



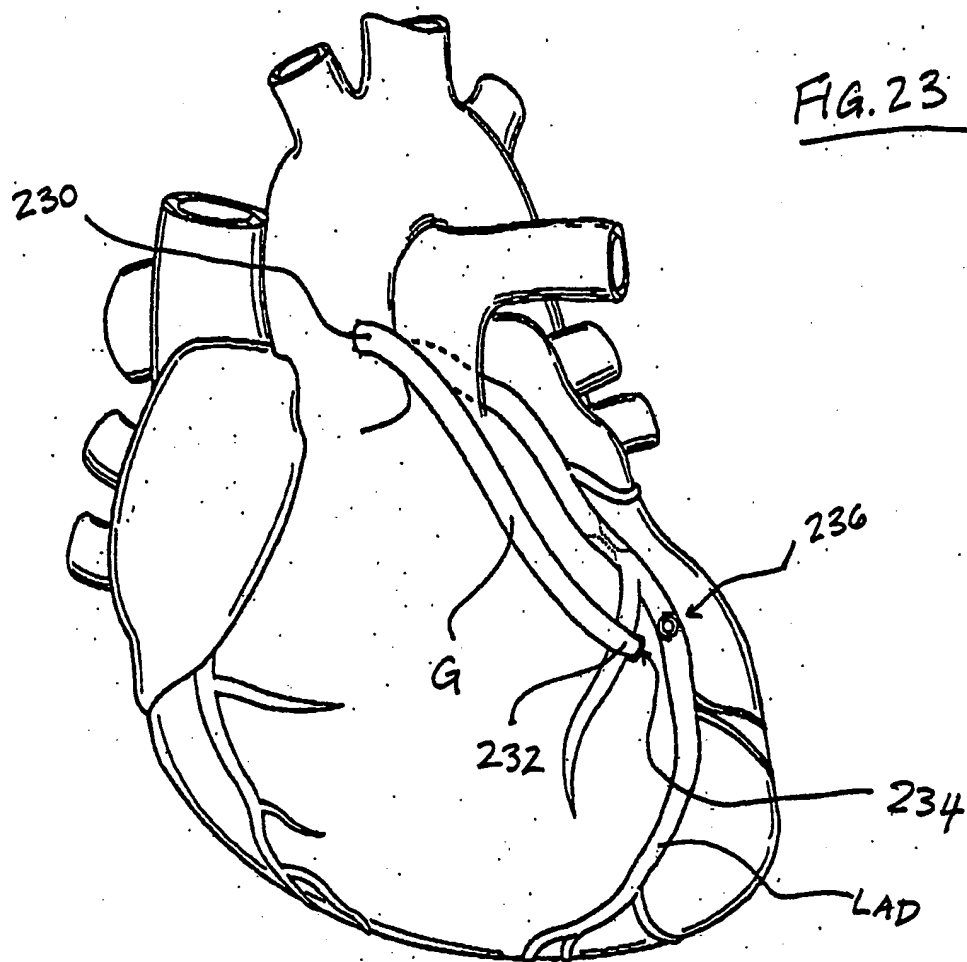
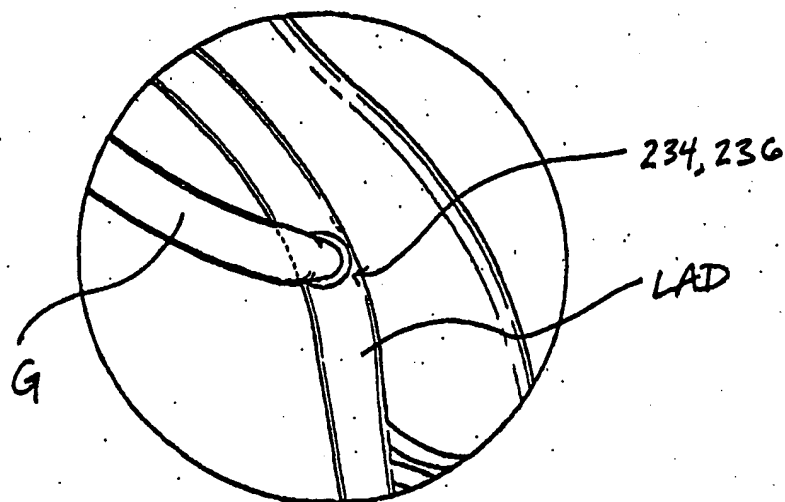
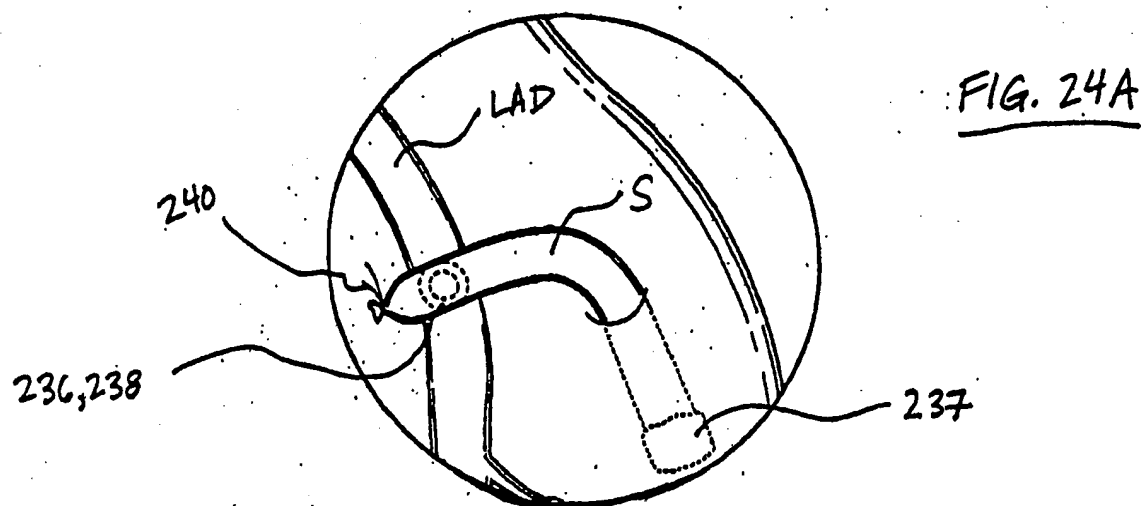
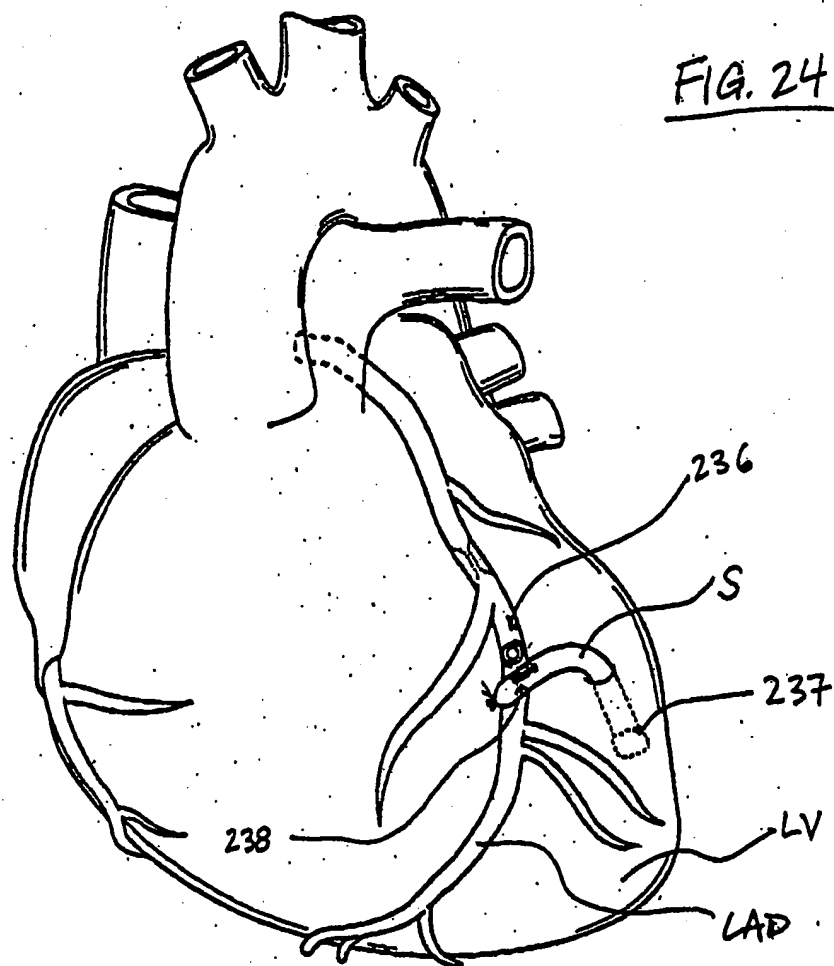


FIG. 23A





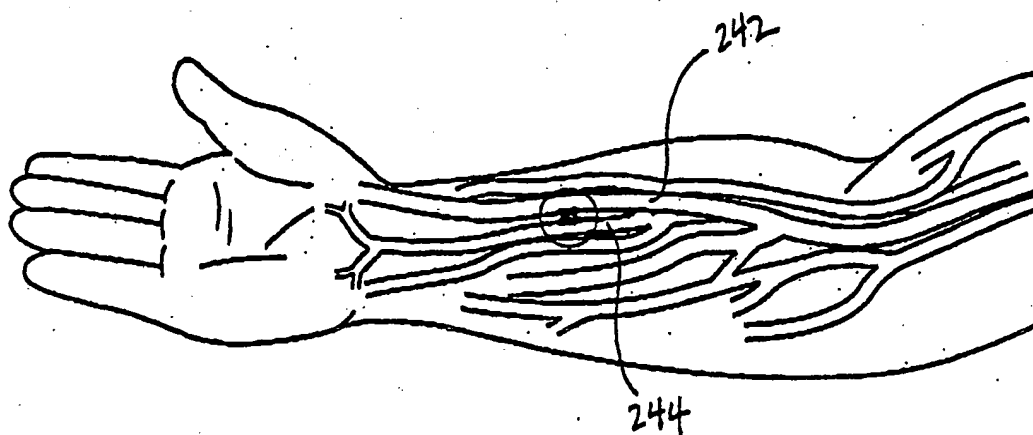


FIG. 25

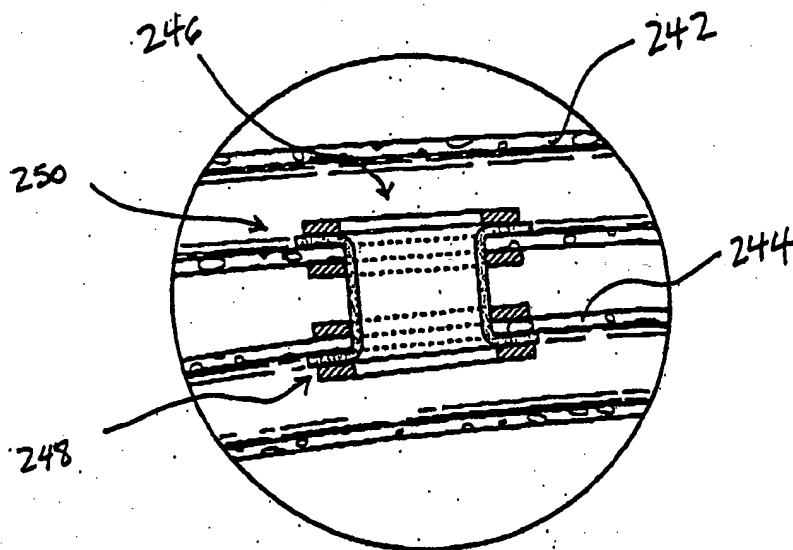


FIG. 25A

FIG. 26A

252

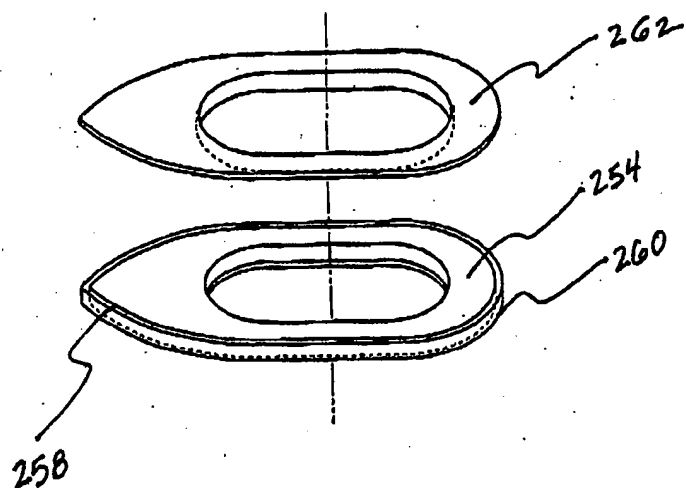
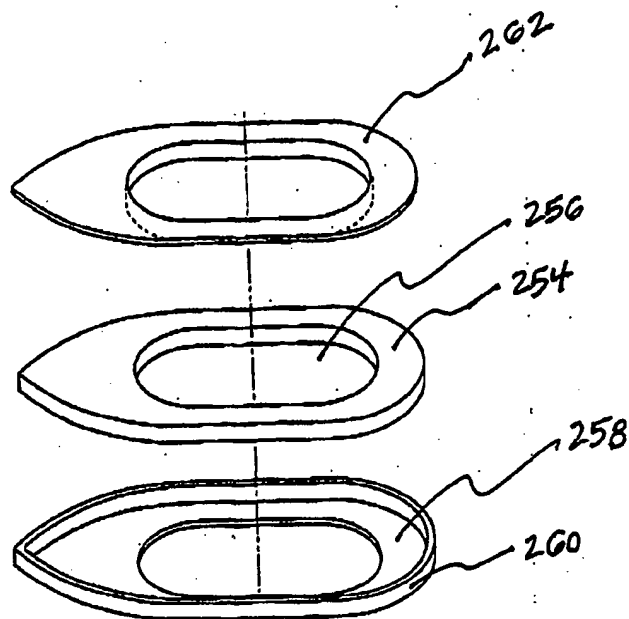


FIG. 26B

FIG. 26C

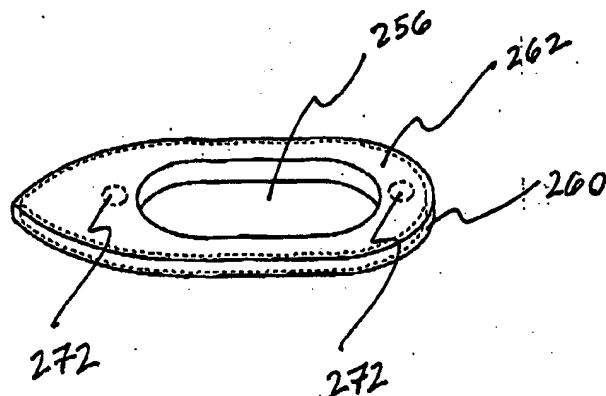


FIG. 27B

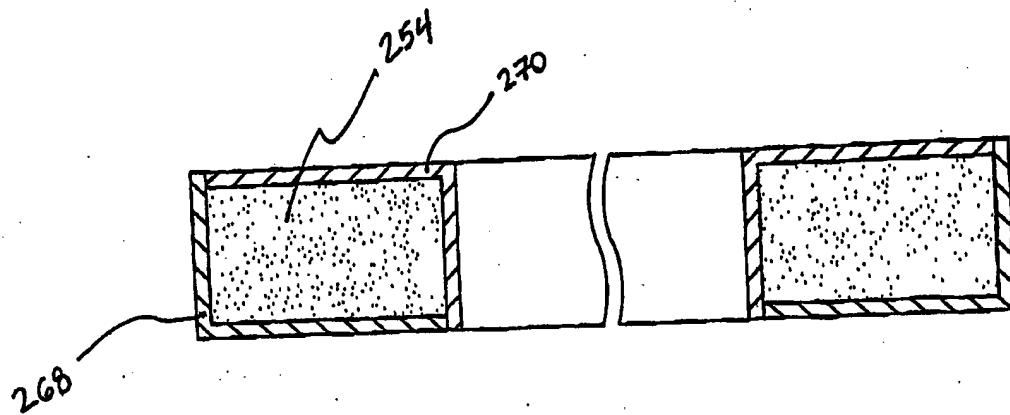


FIG. 27A

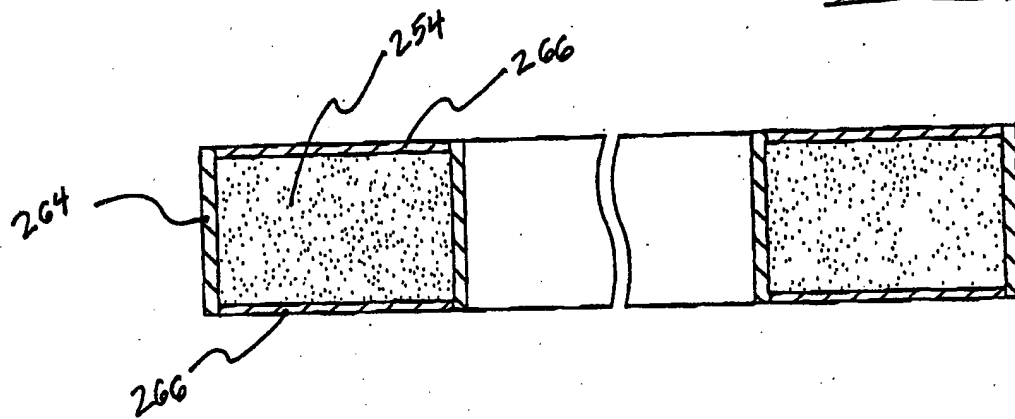


FIG. 26D

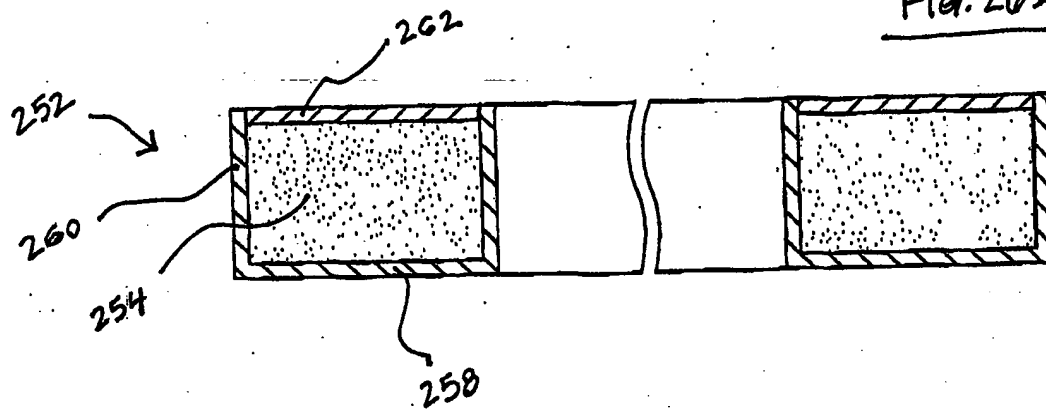


FIG. 28

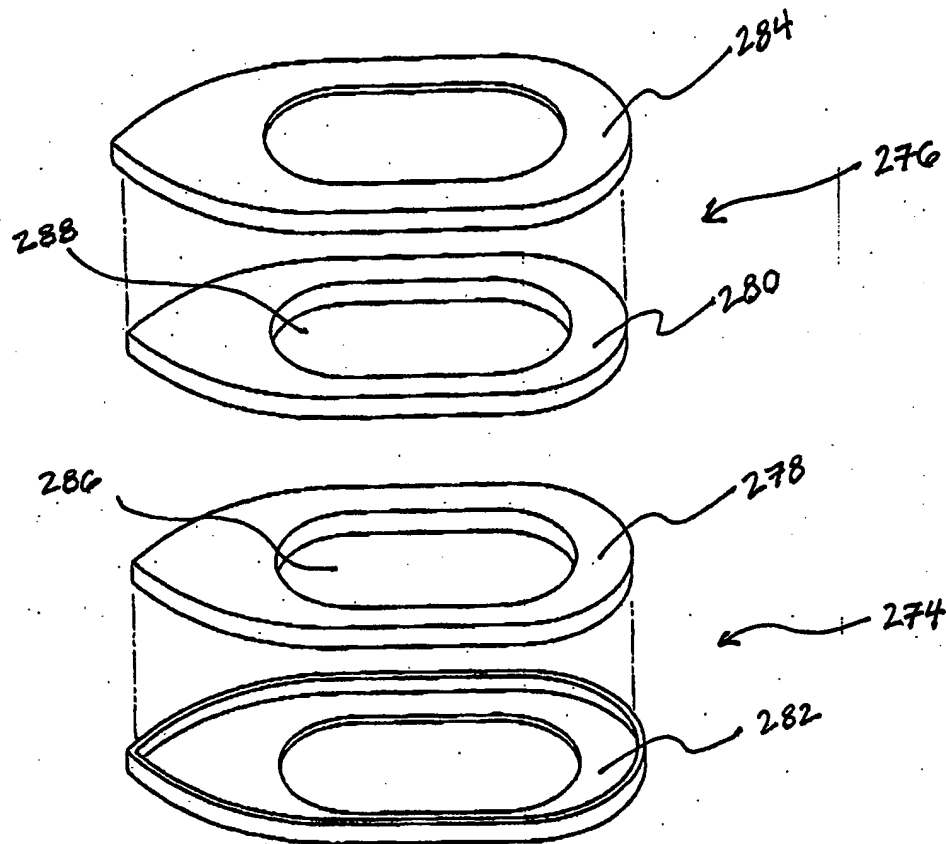
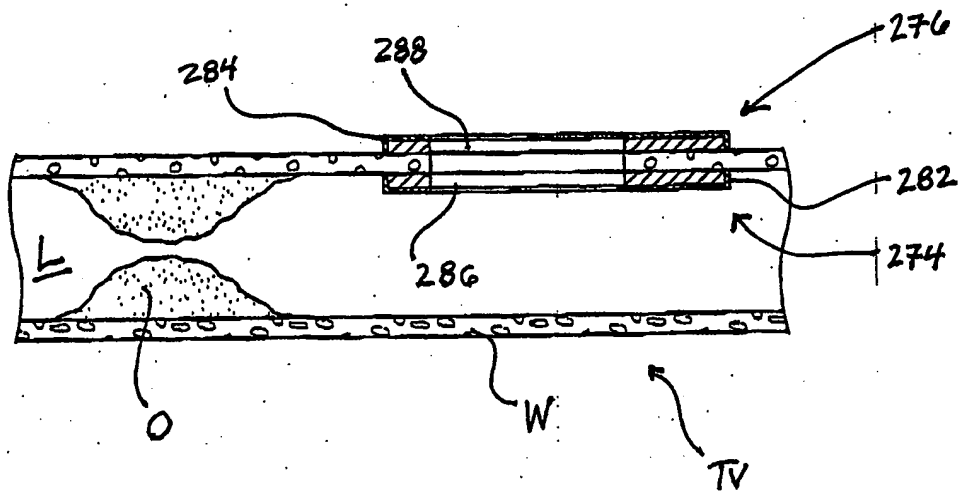
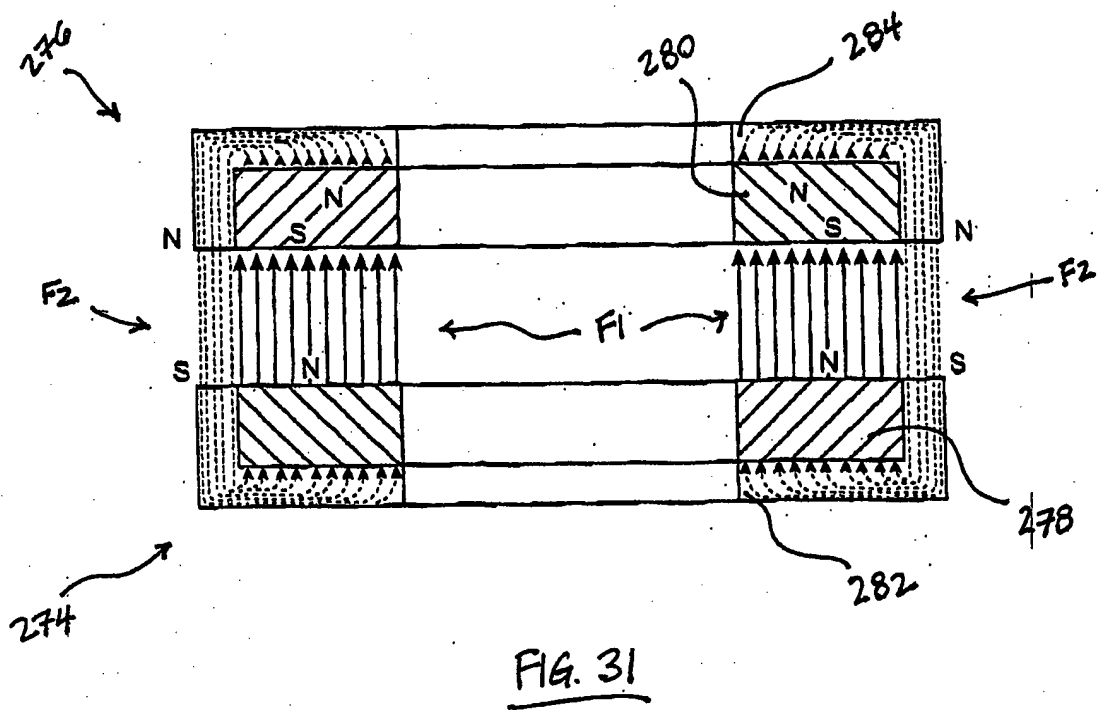
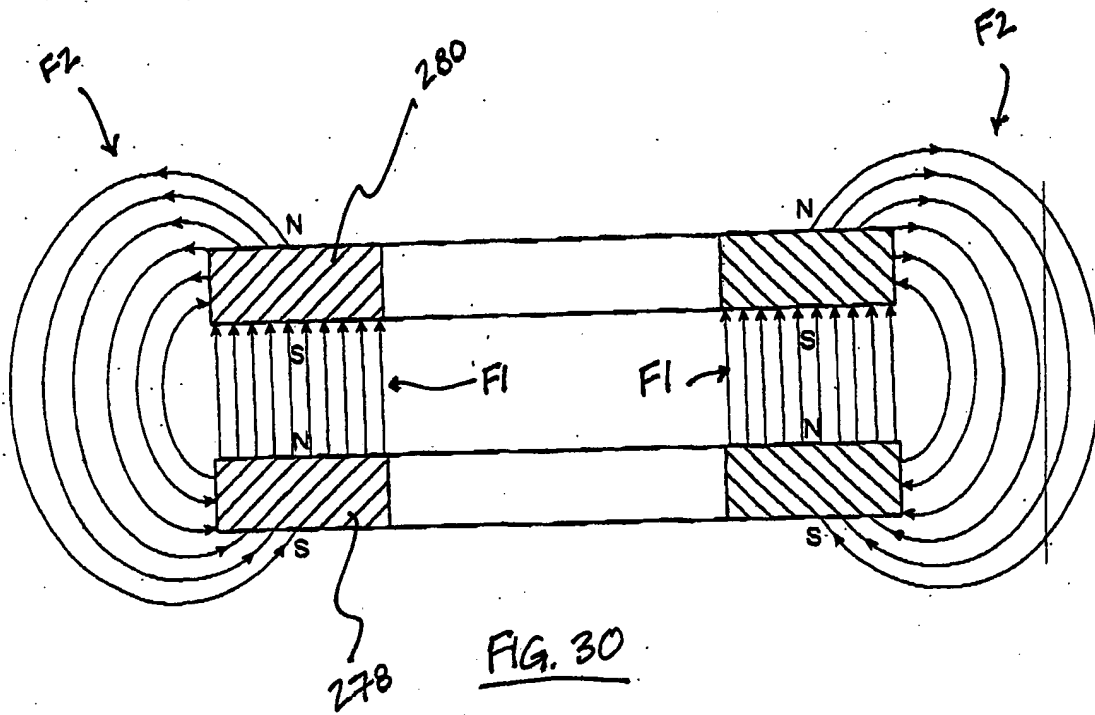


FIG. 29





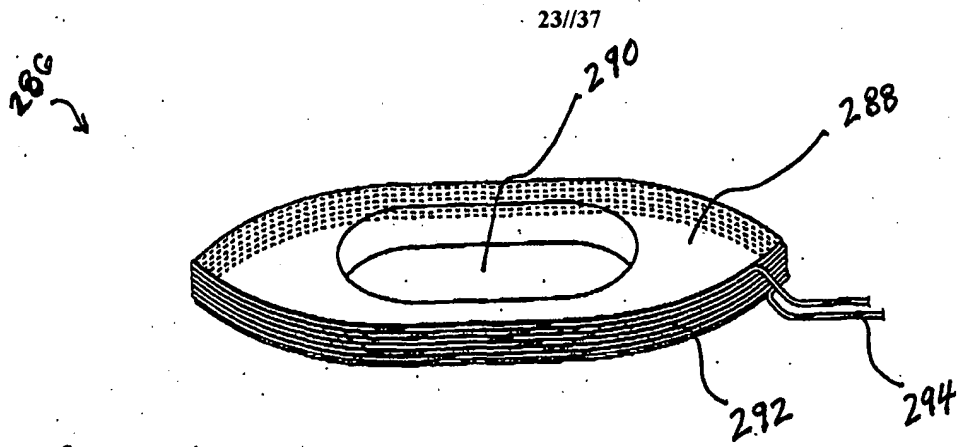


FIG. 32A

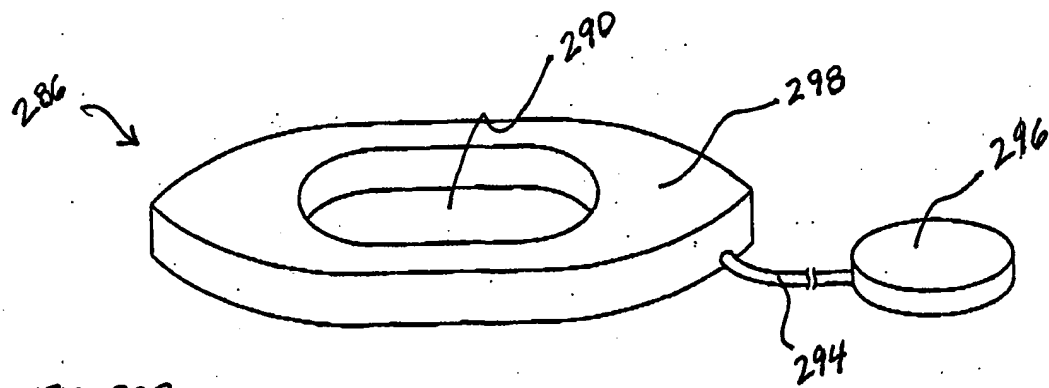


FIG. 32B

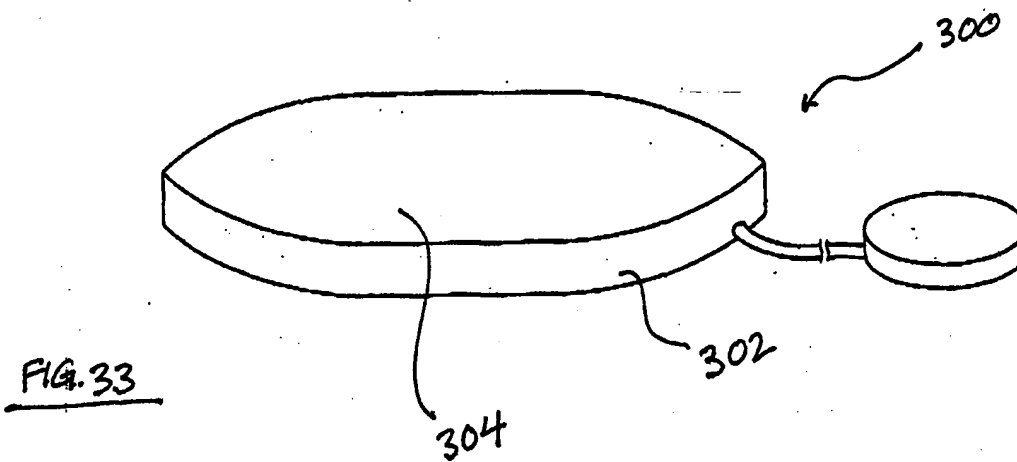


FIG. 33

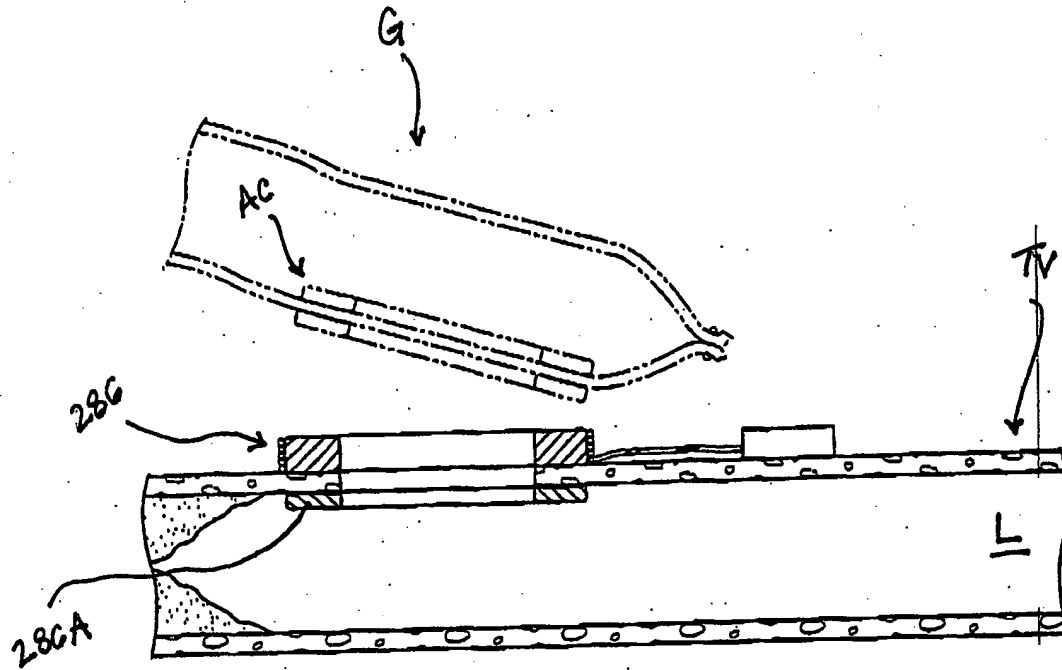


FIG. 34A

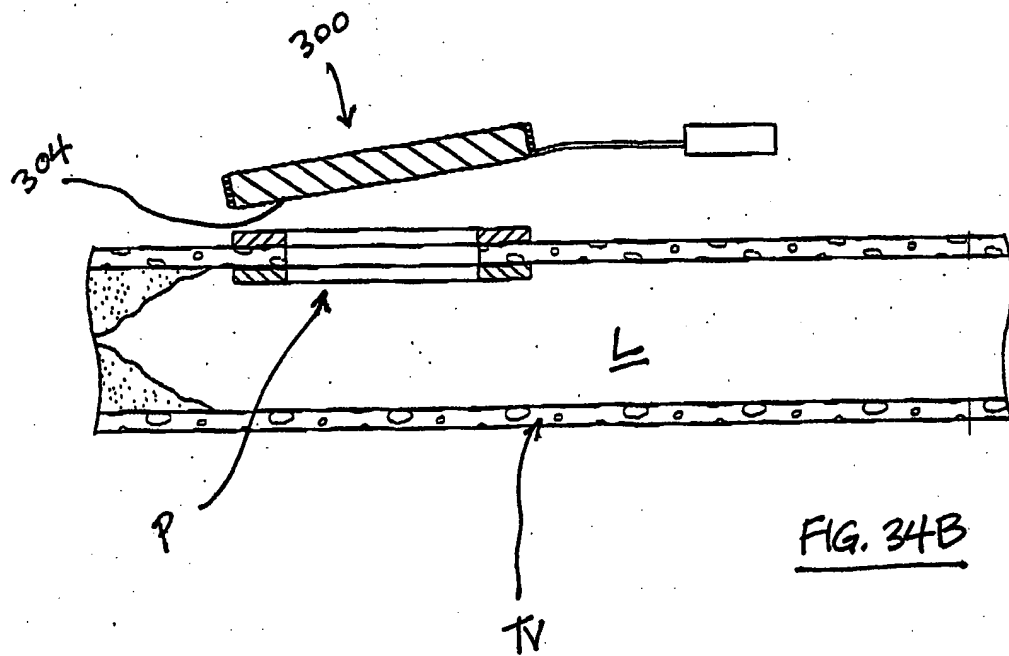


FIG. 34B

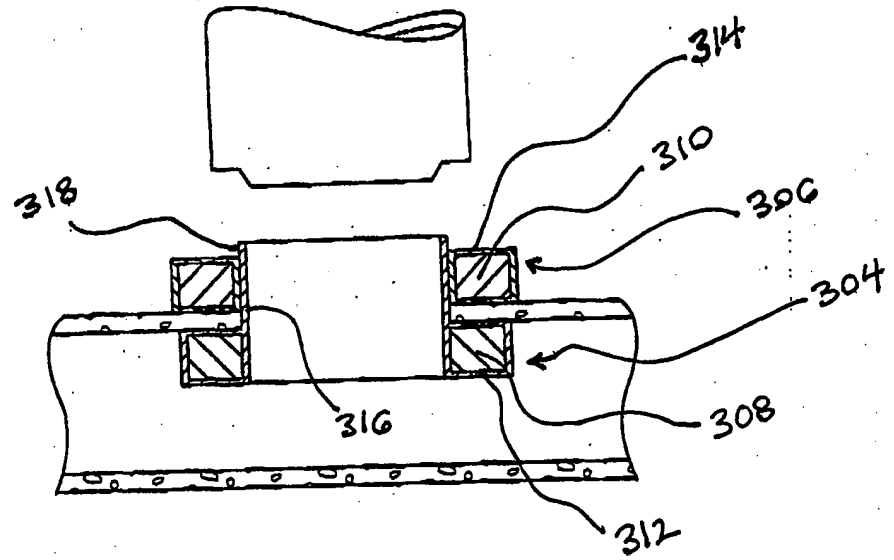


FIG. 35A

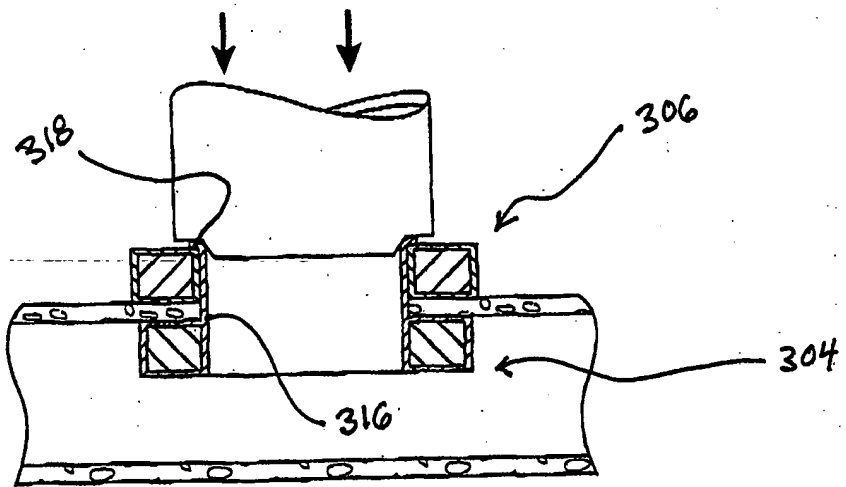


FIG. 35B

FIG. 36A

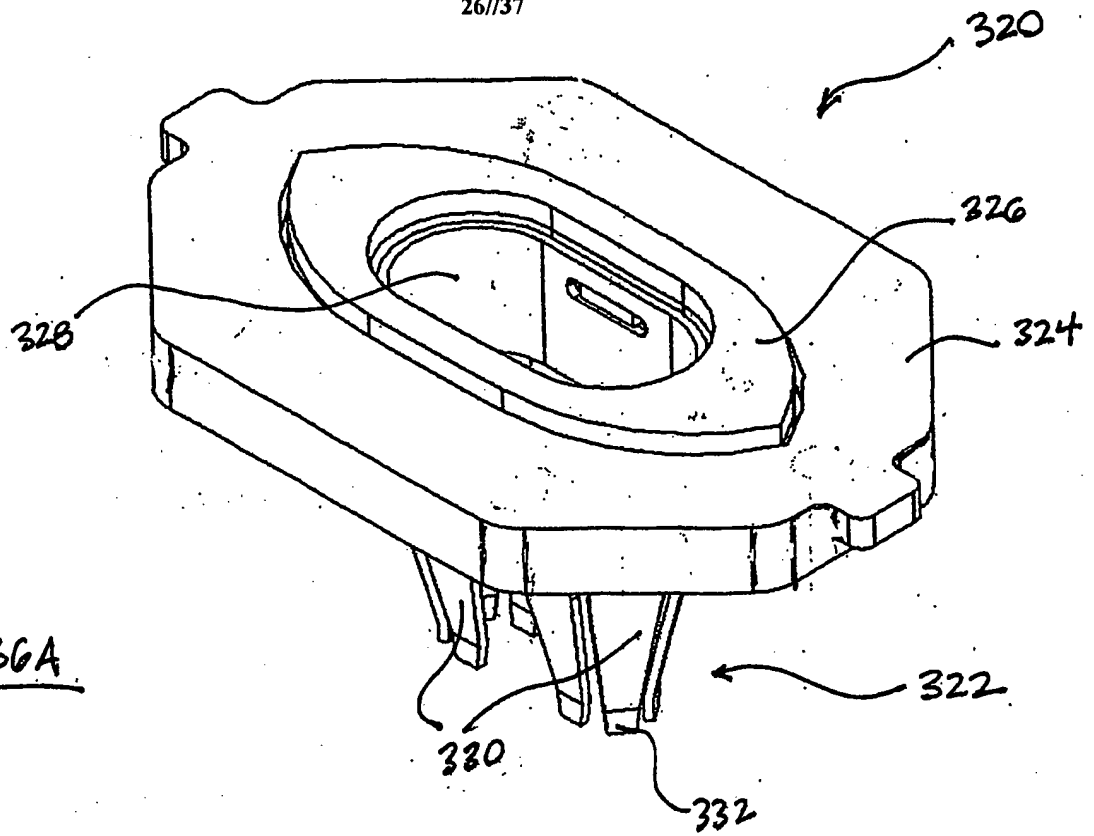
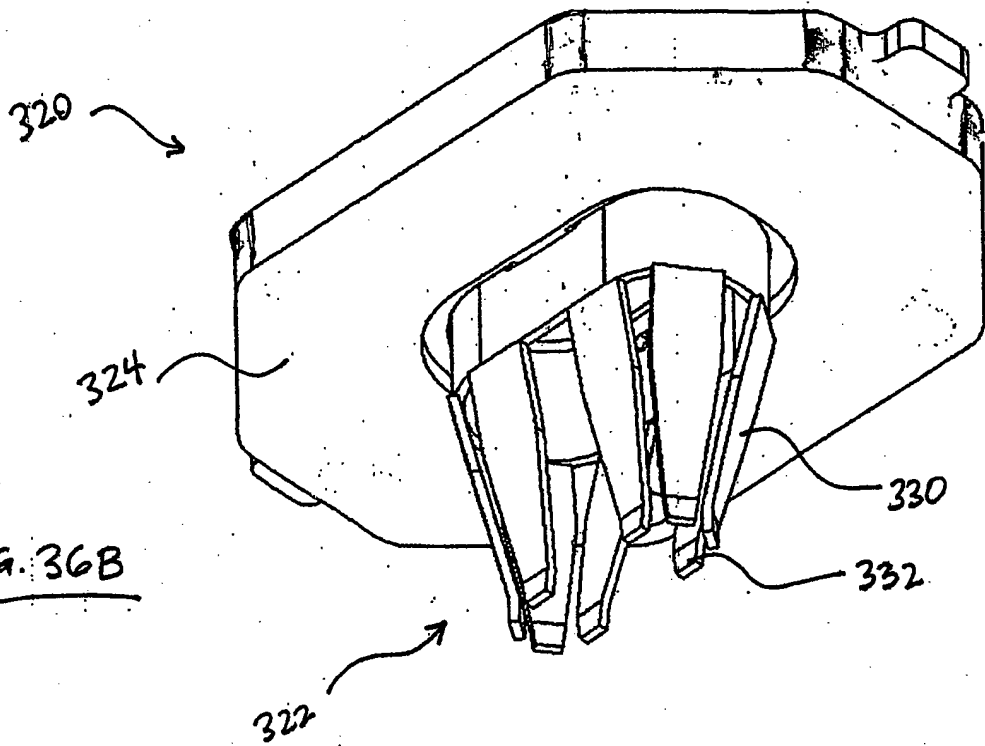
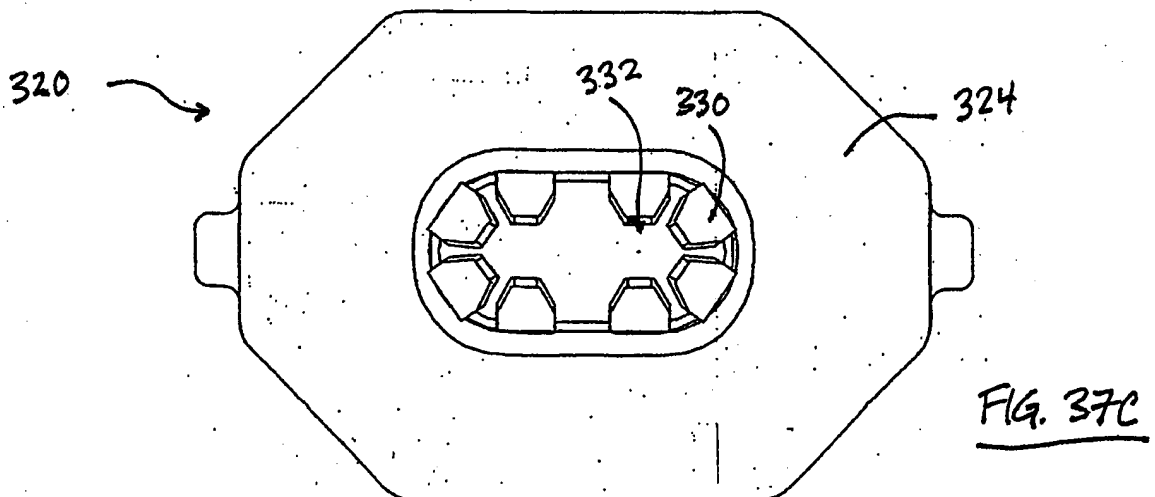
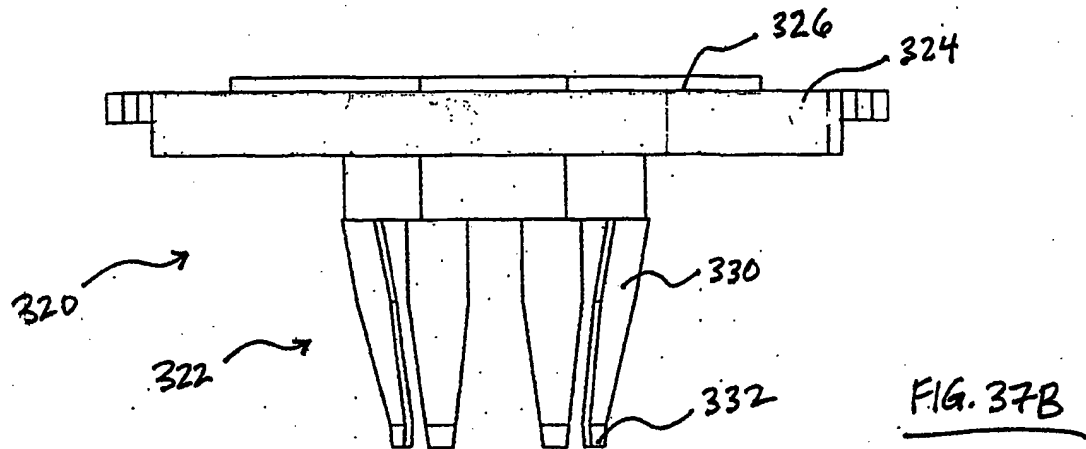
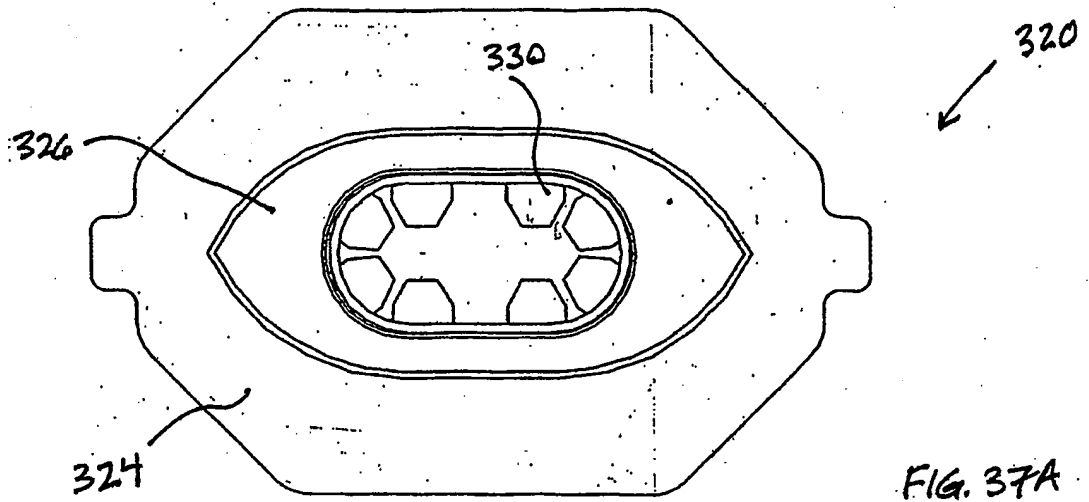
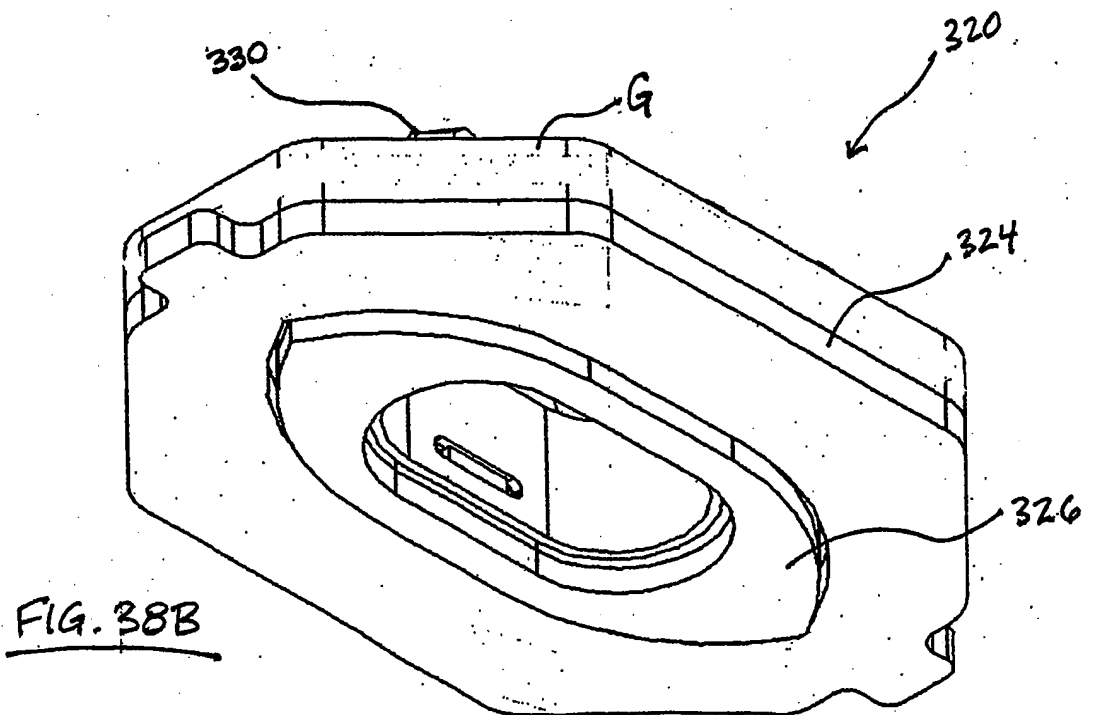
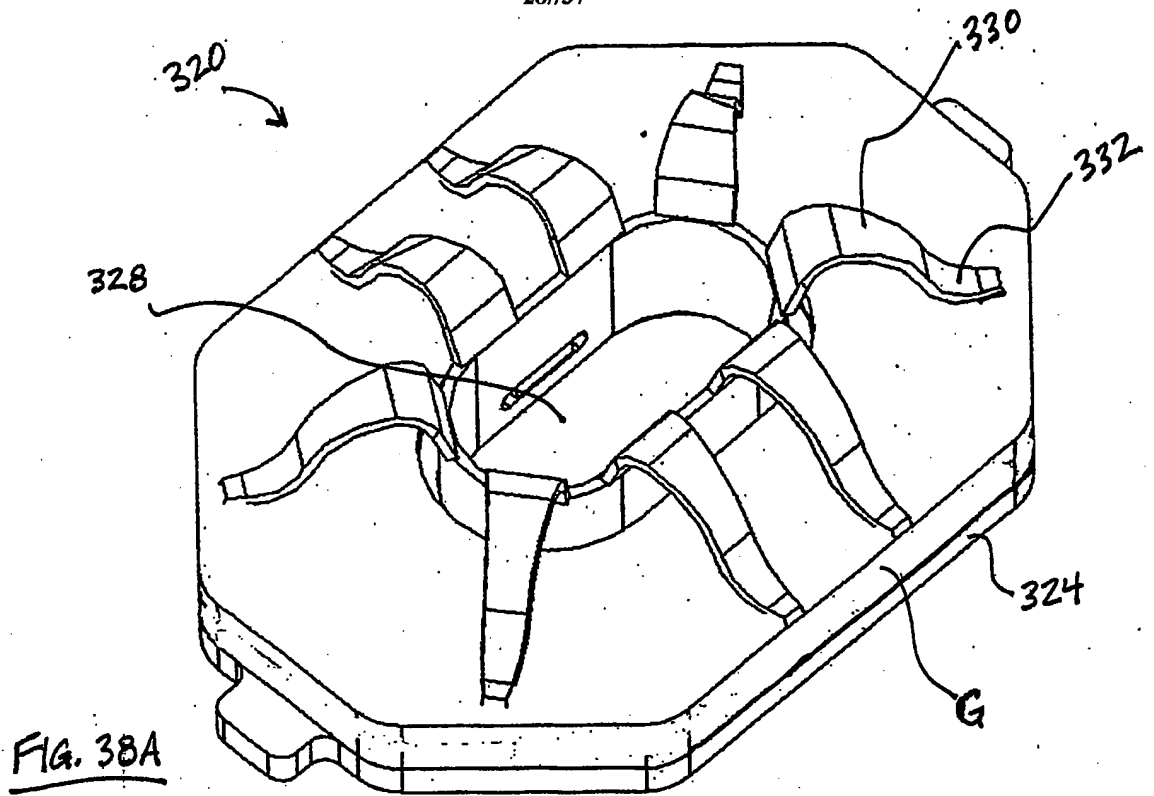
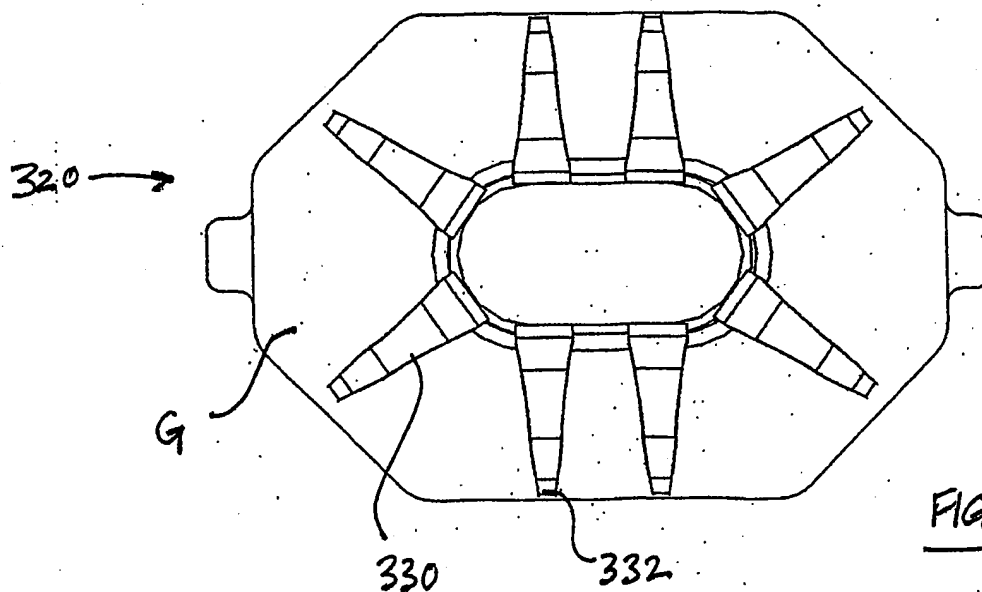
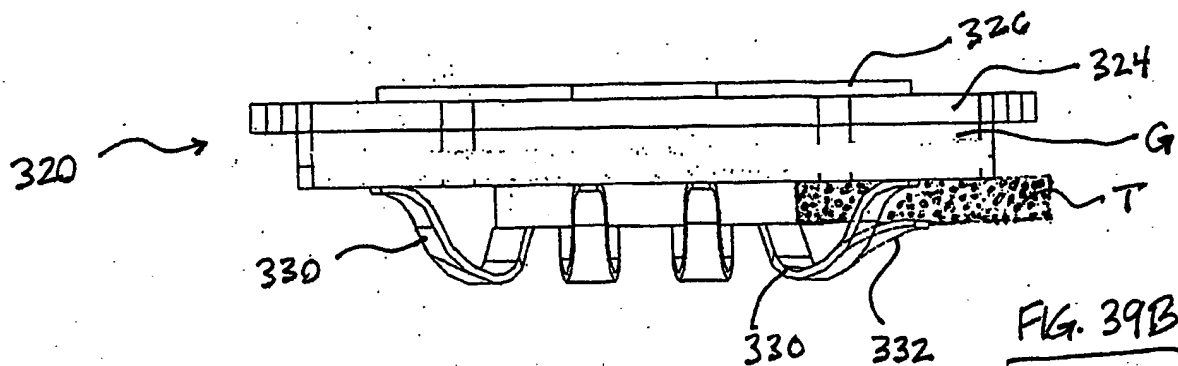
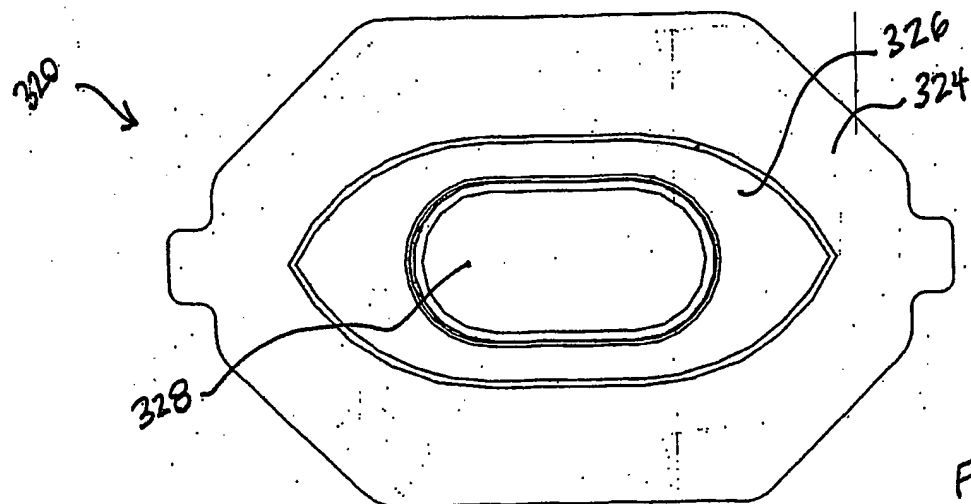


FIG. 36B









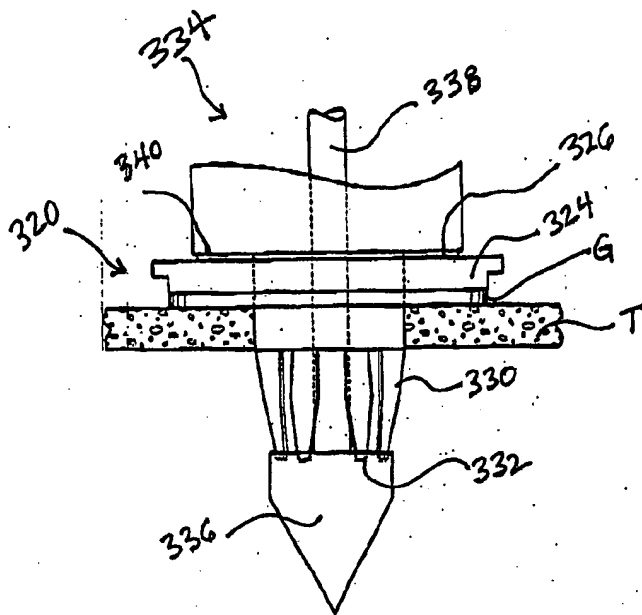


FIG. 40A

FIG. 40B

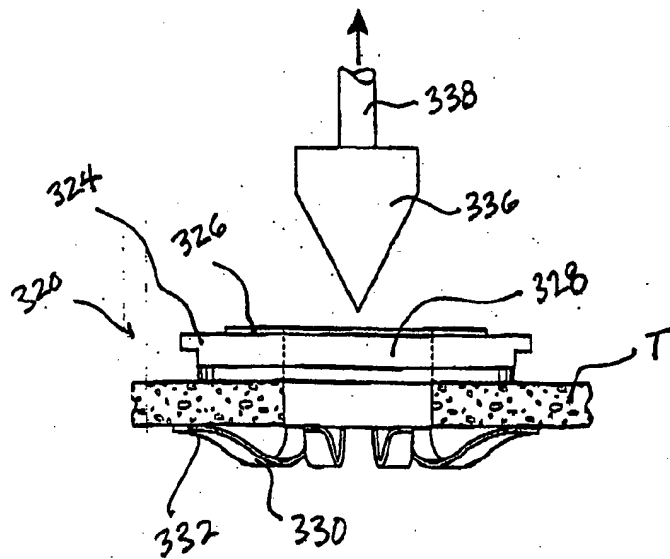
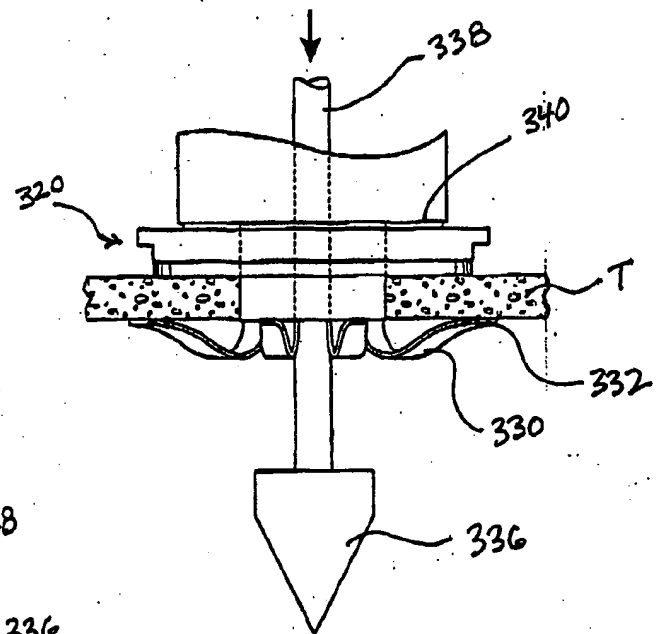


FIG. 40C

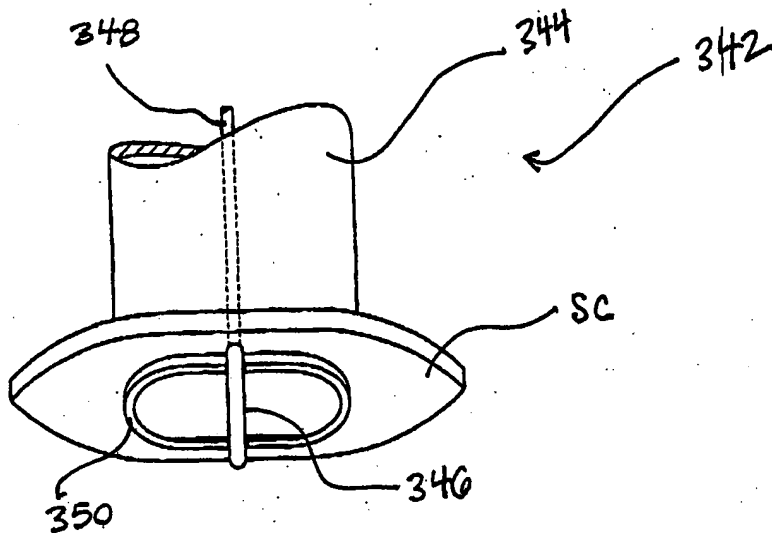


FIG. 41A

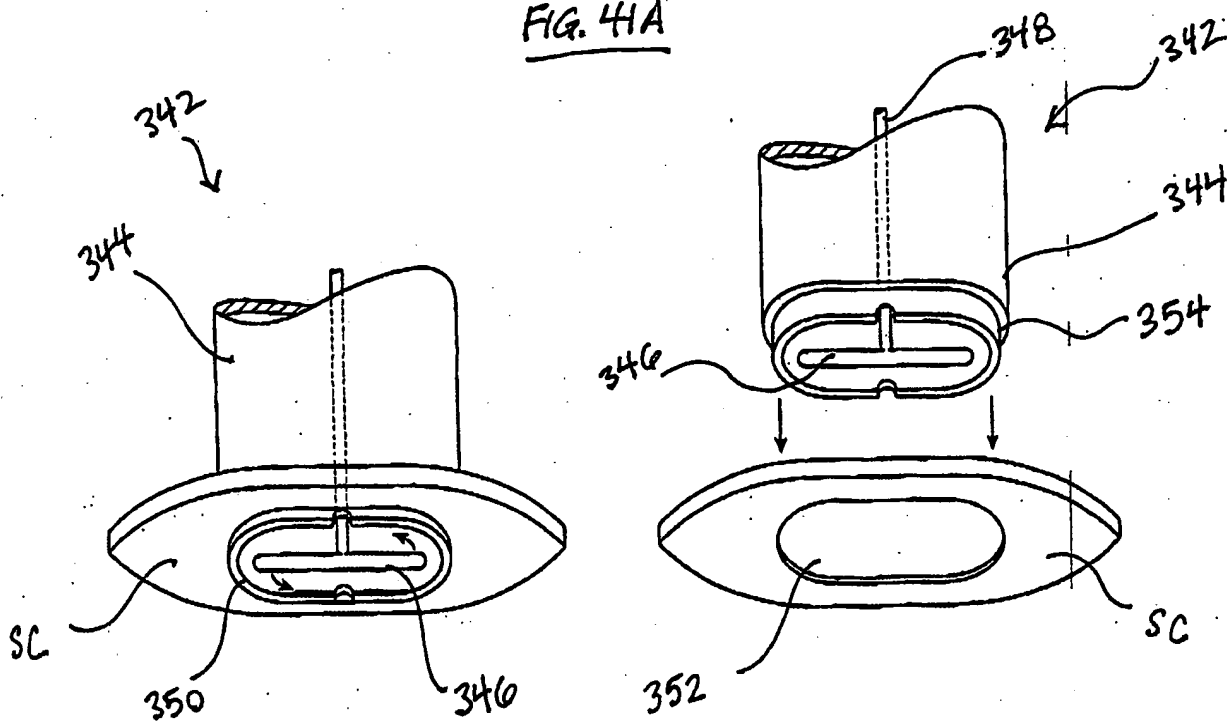


FIG. 41B

FIG. 41C

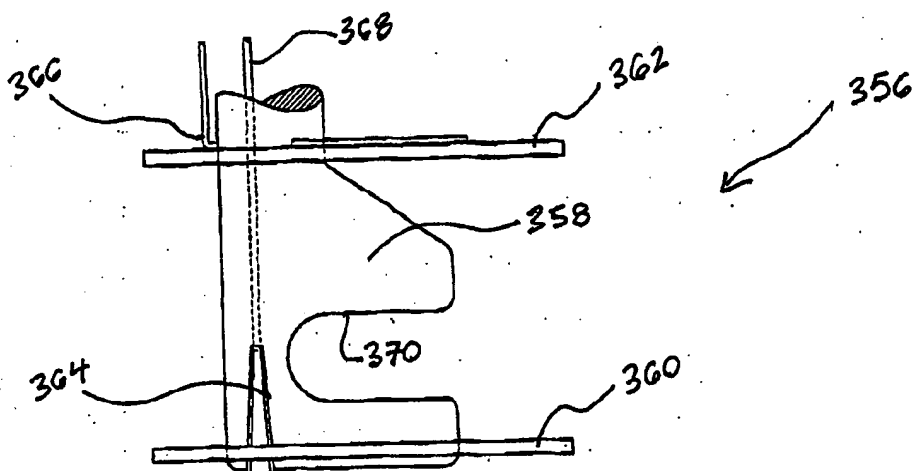


FIG. 42A

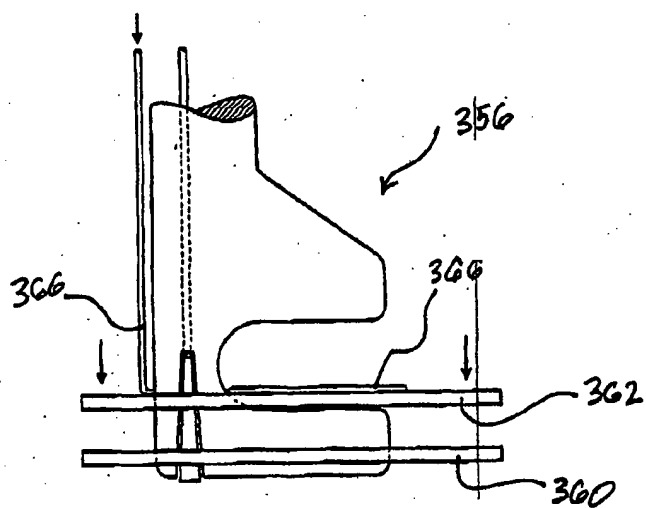


FIG. 42B

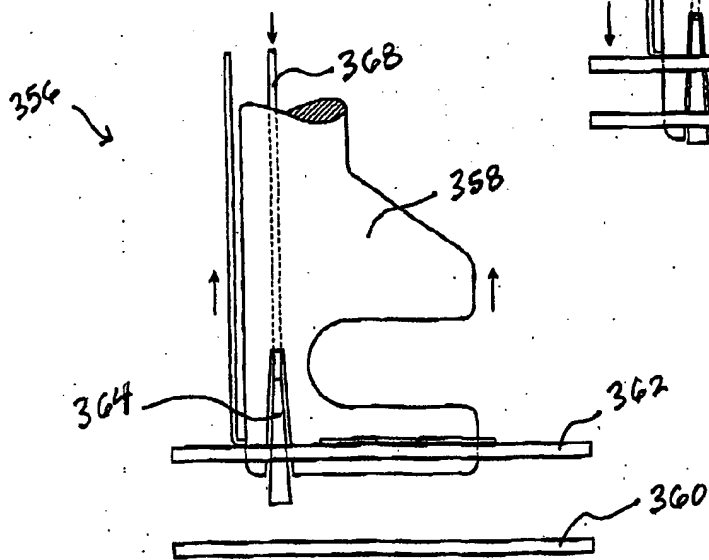
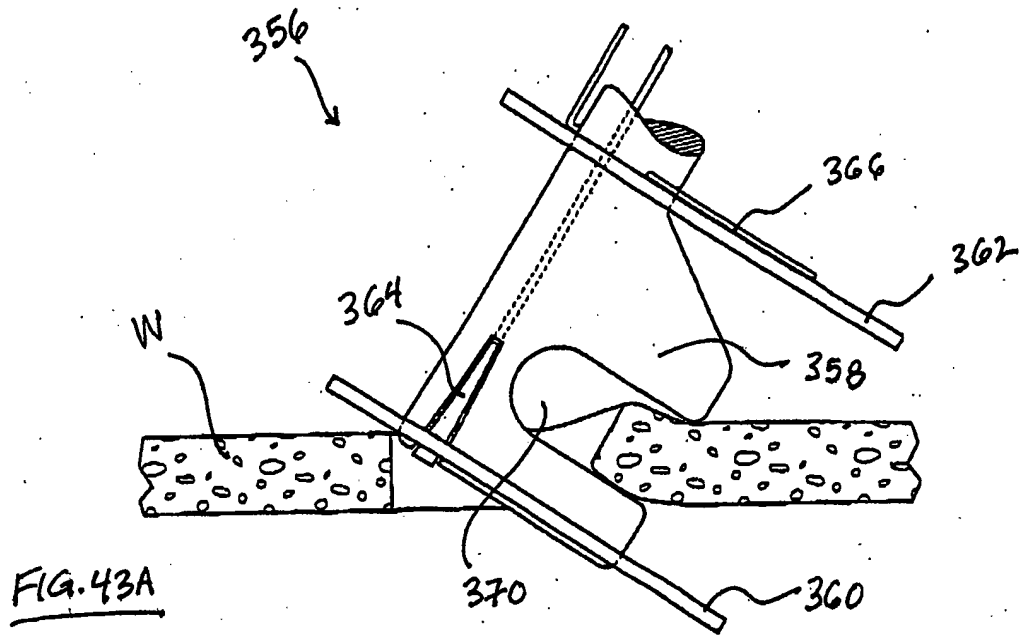


FIG. 42C



34/37

374

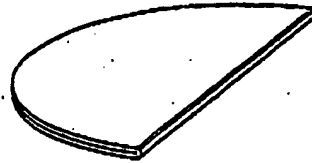
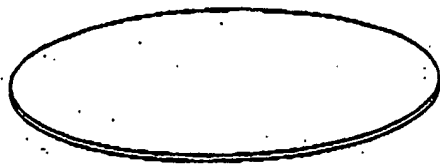
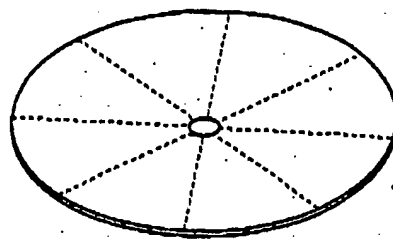


FIG. 44



376

376

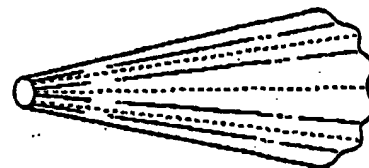
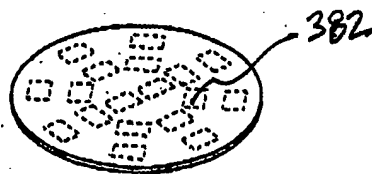
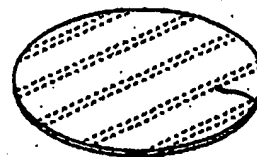


FIG. 45A

FIG. 45B



382



382

FIG. 46A

FIG. 46B

378

380

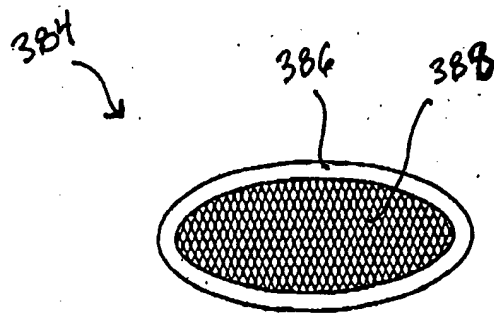


FIG. 46C

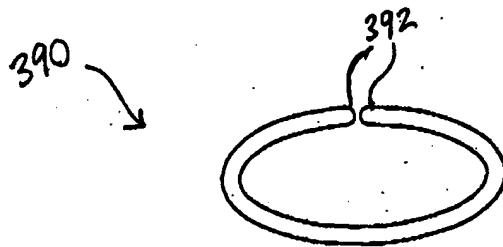


FIG. 46D

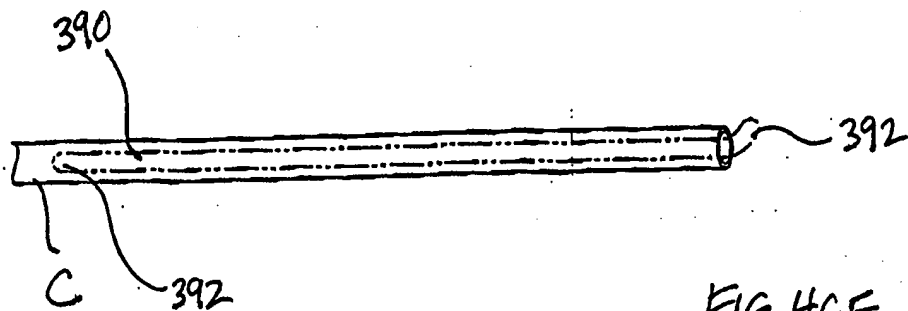


FIG. 46E

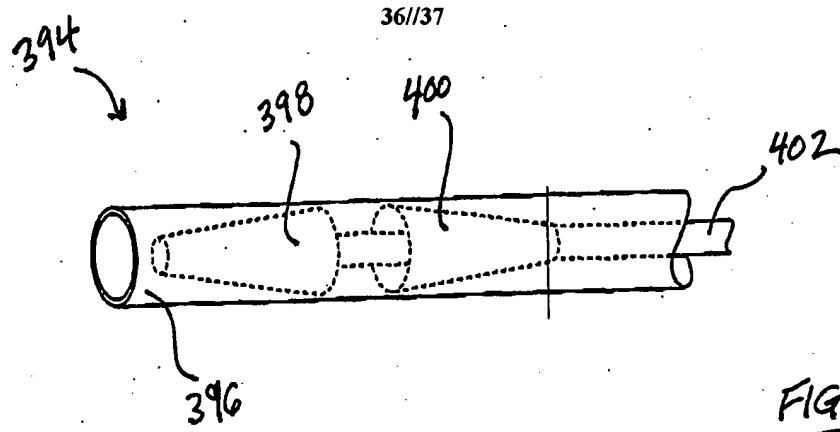


FIG. 47A

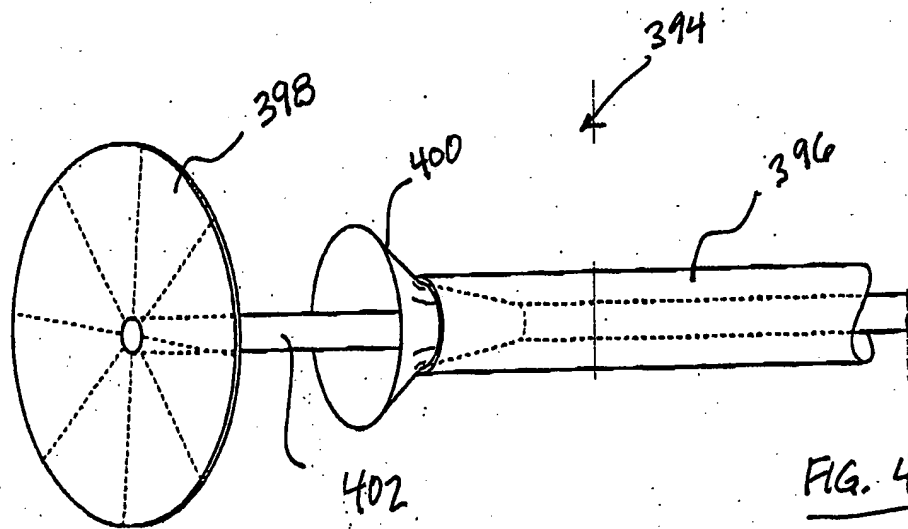


FIG. 47B

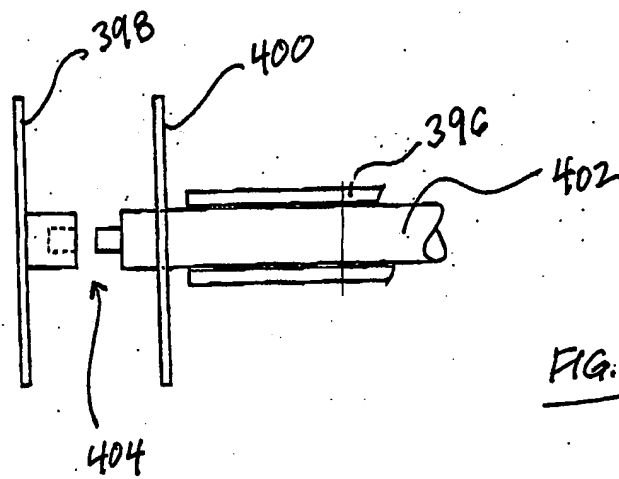
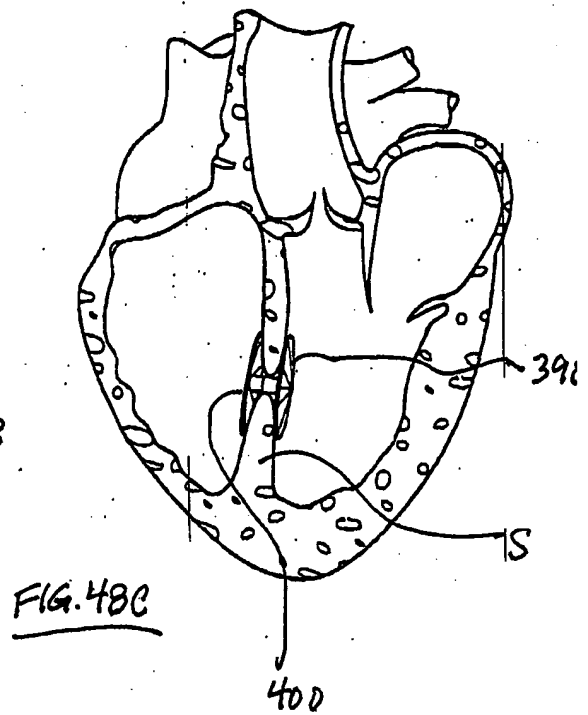
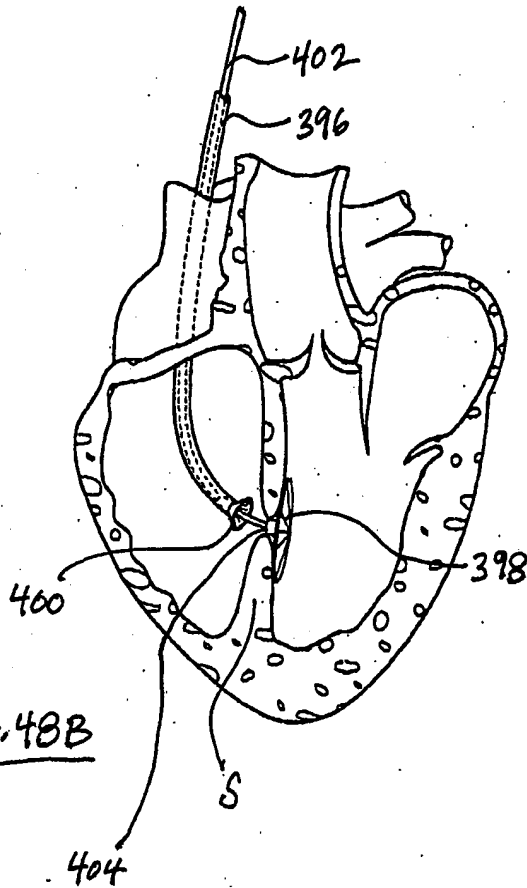
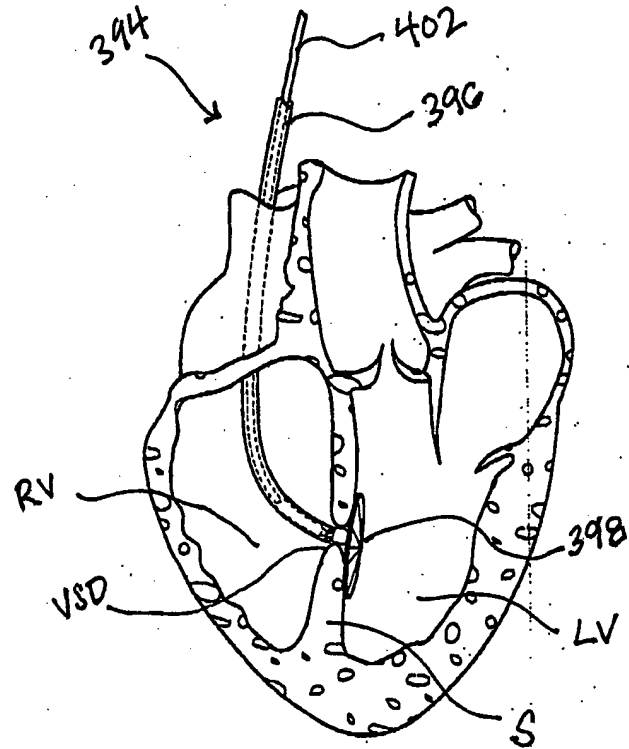


FIG. 47C



International application No.
PCT/US01/25113

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61B 17/11

US CL :606/153

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/151, 153, 215, 216

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EAST BRS

search terms: anastomosis, magnetic

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,690,656 A (COPE et al.) 25 November 1997, fig. 15.	1,2
Y		7
X	OBORA, Y. et al., Nonsuture Microvascular Anastomosis Using Magnet Rings, Neurol. Med. Chir. (Tokyo), 1980, vol. 20, fig. 1.	18,19,21, 22,25,31, 32,43, 46-49

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	
"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E" earlier document published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O" document referring to an oral disclosure, use, exhibition or other means	"G" document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

19 OCTOBER 2001

Date of mailing of the international search report

20 DEC 2001

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

JULIAN W. WOO

Telephone No. (703) 308-0421

CORRECTED VERSION

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
21 February 2002 (21.02.2002)

PCT

(10) International Publication Number
WO 02/013703 A1

(51) International Patent Classification: **A61B 17/11**

(21) International Application Number: PCT/US01/25113

(22) International Filing Date: 10 August 2001 (10.08.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
09/638,805 12 August 2000 (12.08.2000) US
60/255,635 13 December 2000 (13.12.2000) US
09/851,400 7 May 2001 (07.05.2001) US
09/915,226 23 July 2001 (23.07.2001) US

(71) Applicant (for all designated States except US): **VENTRICA, INC.** [US/US]; 5055 Brandin Court, Fremont, CA 94538 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **COLE, David**

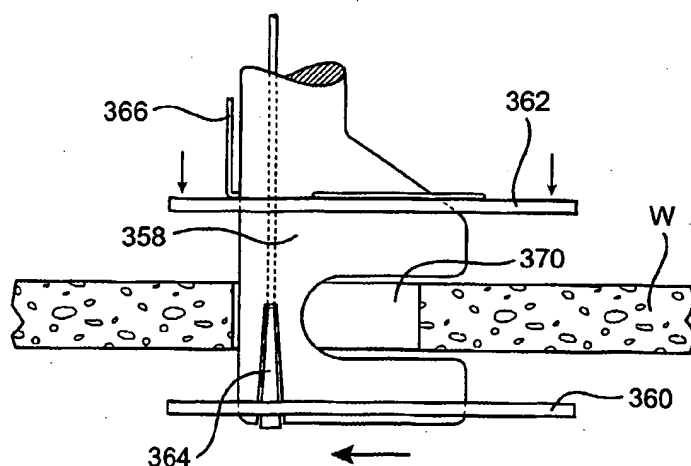
[US/US]; 1550 Lago Street, San Mateo, CA 94403 (US). **CREWS, Samuel** [US/US]; 330 Nimitz Avenue, Redwood City, CA 94061 (US). **REO, Michael** [US/US]; 701 Baltic Circle, Unit 731, Redwood City, CA 94085 (US). **CARSON, Dean** [US/US]; 1652 Yale Drive, Mountain View, CA 94040 (US). **LEPULU, Keke** [US/US]; 117 Vera Avenue #7, Redwood City, CA 94063 (US). **GITTINGS, Darin** [US/US]; 520 South Bayview Avenue, Sunnyvale, CA 94086 (US).

(74) Agent: **LYNCH, Michael**; Hoekendijk & Lynch, LLP, 433 Airport Blvd., Suite 432, Burlingame, CA 94010 (US).

(81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

[Continued on next page]

(54) Title: **MAGNETIC COMPONENTS FOR FORMING ANASTOMOSES AND CREATING PORTS IN VESSELS**



(57) Abstract: Methods and devices for forming an anastomosis between hollow bodies utilize magnetic force to couple anastomotic components (360, 362) and connect the lumens of the hollow bodies. End-to-side, side-to-side and end-to-end anastomoses can be created with or without a mechanical connection between the components (360, 362). The securing components (360, 362) have the ability to produce a magnetic field and may include materials or assemblies. A component (278, 280) may also be used to form a port into the lumen of a vessel, the component (278, 280) being attached to the vessel by mechanical and/or magnetic means. Magnetic components (278, 280) may include means (282, 284) for concentrating the magnetic flux between respective components (278, 280) to increase the attraction force, thereby enhancing the security of the anastomosis. Components (398, 400) having an occlusion surface may be used to close an opening in tissue, e.g., an atrial septal defect.

WO 02/013703 A1



(84) **Designated States (regional):** ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— with international search report

(48) **Date of publication of this corrected version:**

27 March 2003

(15) **Information about Correction:**

see PCT Gazette No. 13/2003 of 27 March 2003, Section II

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

MAGNETIC COMPONENTS FOR FORMING ANASTOMOSES AND CREATING PORTS IN VESSELS

CROSS-REFERENCE TO RELATED APPLICATIONS

5 This application is a continuation-in-part of application Serial No. 09/562,599, filed April 29, 2000 and entitled "Methods and Devices Using Magnetic Force to Form an Anastomosis Between Hollow Bodies," the entire subject matter of which is incorporated by reference herein.

BACKGROUND OF THE INVENTION

Field of the Invention

10 The invention relates to methods and devices for forming anastomoses between two hollow bodies, creating magnetic ports in vessels, and closing openings in tissue, for example, atrial or ventricular septal defects.

Description of Related Art

15 Despite the considerable advances that have been realized in cardiology and cardiovascular surgery, heart disease remains the leading cause of death throughout much of the world. Coronary artery disease, or arteriosclerosis, is the single leading cause of death in the United States today. As a result, those in the cardiovascular field continue to search for new treatments and improvements to existing treatments.

20 Despite the considerable advances that have been realized in cardiology and cardiovascular surgery, heart disease remains the leading cause of death throughout much of the world. Coronary artery disease, or arteriosclerosis, is the single leading cause of death in the United States today. As a result, those in the cardiovascular field continue to search for new treatments and improvements to existing treatments.

25 Coronary artery disease is currently treated by interventional procedures such as percutaneous transluminal coronary angioplasty (PTCA), coronary stenting and atherectomy, as well as surgical procedures including coronary artery bypass grafting (CABG). The goal of these procedures is to reestablish or improve blood flow through occluded (or partially occluded) coronary arteries, and is accomplished, for example, by
30 enlarging the blood flow lumen of the artery or forming a bypass that allows blood to circumvent the occlusion. What procedure(s) is used typically depends on the severity and

location of the blockage. When successful, these procedures restore blood flow to myocardial tissue that had not been sufficiently perfused due to the occlusion.

Another proposed treatment places the target vessel, e.g., a coronary artery, in direct fluid communication with a heart chamber containing blood, for example, the left
5 ventricle. Blood flows from the ventricle into a conduit that is in fluid communication with the artery; as such, this treatment may be described as a ventricular bypass procedure. Benefits of this procedure include obviating the need to manipulate the aorta, for example, as is done when a side-biting clamp is used in a typical CABG procedure to create a proximal anastomosis between the bypass graft and the aorta. Clamping or otherwise manipulating the
10 aorta places the patient at risk in some cases due to the likelihood that such manipulation will release embolic material into the bloodstream. Some challenges associated with this procedure include delivering and deploying the conduit in the patient's body, properly positioning the conduit with respect to the heart chamber and the target vessel, and obtaining beneficial flow characteristics through the conduit and the target vessel.

15 A particularly challenging task that must be performed during CABG procedures (as well as some ventricular bypass procedures) is suturing the conduit to one or more vessels. As an example, one end of the conduit may be sutured to a source of blood, such as the aorta, a heart chamber or a blood vessel, while the other end of the conduit is sutured to the target vessel, such as a coronary artery or another blood vessel. The small
20 diameter of the vessels involved (typically from 1 mm to 4 mm) makes creating a handsewn anastomosis a highly technical and time-consuming procedure. The difficulty in forming the sutured anastomosis is exacerbated when access to the target vessel is restricted or limited, as in a minimally invasive or percutaneous procedure. This problem also arises in non-cardiovascular applications that utilize handsewn anastomoses, for example, treating
25 peripheral vascular disease or injury, creating AV (arteriovenous) shunts, etc.

While those in the art have proposed various anastomotic couplings intended to replace a sutured anastomosis, none has performed well enough to receive any significant level of acceptance in the field. Many of the proposed couplings penetrate or damage the target vessel wall acutely or chronically, do not remain patent, fail to produce a fluid-tight
30 seal between the conduit and vessel, or are simply too cumbersome and difficult to deliver or deploy.

While those in the art have proposed various anastomotic couplings intended to replace a sutured anastomosis, none has performed well enough to receive any significant

level of acceptance in the field. Many of the proposed couplings penetrate or damage the target vessel wall acutely or chronically, do not remain patent, fail to produce a fluid-tight seal between the conduit and vessel, or are simply too cumbersome and difficult to deliver or deploy.

5 Accordingly, there is a need in the art for methods and devices for forming a reliable anastomosis between hollow bodies in a relatively quick, easy and repeatable manner, for creating a port in a vessel for use in forming the anastomosis, and for closing openings in tissue, either permanently or temporarily.

SUMMARY OF THE INVENTION

10 According to one embodiment the invention provides a device for forming a magnetic port in a hollow body having a lumen. The device includes a component capable of producing a magnetic field and having an opening configured to be placed in communication with the lumen of the hollow body, and a housing disposed on an exterior of the component. The housing provides a substantially sealed enclosure containing the component and is
15 formed of a biocompatible material.

 Another embodiment provides a device adapted to be coupled to tissue using magnetic force. The device includes a first securing component that is capable of producing a magnetic field and is adapted to attract a second securing component also capable of producing a magnetic field. A magnetic force-increasing mechanism is provided for
20 increasing the magnetic force attracting the first and second securing components when they are positioned in proximity to each other.

 Another embodiment provides a device adapted to be coupled to a blood vessel having a lumen so as to produce a magnetic field adjacent the blood vessel. The device includes at least one securing component that is sized and configured to be secured to
25 a blood vessel having a lumen and is capable of producing a magnetic field. The securing component has an indicator that indicates the polarity of the magnetic field to a user carrying out a procedure on the blood vessel.

 Another embodiment provides a device for forming a port in a first hollow body having a lumen. The device includes a securing component having an opening adapted
30 to be placed in communication with an opening in the wall of the first hollow body e in communication with the lumen, and a mechanical attachment portion configured to secure the

component to the first hollow body in a desired position. The securing component is configured to produce a magnetic field adjacent the opening in the first hollow body.

Another embodiment provides a delivery device in combination with a component for forming an anastomosis. The combination includes at least one component
5 having an opening adapted to be placed in communication with a lumen of a vessel in a patient's body, the component being capable of producing a magnetic field, and a delivery device including a support portion supporting the component. The delivery device has a retaining portion that is movable with respect to the support portion and is placed in a first position to retain the component and moved from the first position to release the component.
10 The retaining portion is movable with respect to the support portion in either an axial or rotary direction.

Another embodiment of the invention provides a method for increasing the magnetic force between first and second anastomotic securing components. The method is performed by providing first and second anastomotic securing components each of which is
15 capable of producing a magnetic field, the first and second securing components having respective openings adapted to be placed in communication with each other, and increasing the magnetic force between the first and second securing components by concentrating magnetic flux therebetween.

According to another embodiment of the invention a method for coupling a
20 securing component to a target vessel in order to form a magnetic port communicating with a lumen of the target vessel. This method is performed by providing at least one securing component capable of producing a magnetic field and having an opening adapted to be placed in communication with the lumen of the target vessel, coupling the one securing component to the target vessel with the opening in the one securing component communicating with the
25 target vessel lumen, and, prior to completing the coupling step, confirming the orientation of the polarity of the magnetic field.

Another embodiment of the invention provides a method for forming a magnetic port in a first hollow body located within a patient, the first hollow body having a lumen. The method is carried out by forming an opening in a wall of the first hollow body,
30 the opening extending into the lumen of the first hollow body, providing a first securing component capable of producing a magnetic field and having an opening adapted to be placed in communication with the opening in the wall of the first hollow body, and coupling the first

securing component to the first hollow body by a mechanical attachment to form a magnetic port in the first hollow body.

BRIEF DESCRIPTION OF THE DRAWING FIGURES

Other features, aspects, benefits and advantages of the invention will be appreciated from the following detailed description of exemplary embodiments thereof taken in conjunction with the following Figures, wherein:

Figs. 1-5 are perspective views of anastomotic securing components constructed according to various embodiments of the invention;

Fig. 6 is a perspective view showing two hollow bodies adapted to be joined in communication via an end-to-side anastomosis;

Fig. 7 is a perspective view showing two hollow bodies adapted to be joined in communication via a side-to-side anastomosis;

Fig. 8 is a perspective view showing two hollow bodies adapted to be joined in communication via an end-to-end anastomosis;

Fig. 9 is a perspective view of the two hollow bodies shown in Fig. 6 along with an anastomotic system including anastomotic securing components constructed according to one embodiment of the invention;

Fig. 9A is a sectional view taken along line A-A in Fig. 9;

Fig. 10A is a section view similar to Fig. 9A but including alternative anastomotic securing components used to join the two hollow bodies;

Fig. 10B is a section view similar to Fig. 10A including other alternative anastomotic securing components for joining the two hollow bodies;

Fig. 10C is a section view similar to Fig. 10A but showing an alternative attachment between a hollow body and an anastomotic securing component;

Fig. 10D is a section view similar to Fig. 10C showing another alternative attachment between the hollow body and a securing component;

Fig. 11A is a transverse sectional view taken through an end-to-side anastomosis formed according to one embodiment of the invention;

Fig. 11B is a transverse sectional view taken through an end-to-side anastomosis formed according to another embodiment of the invention;

Fig. 12 is a perspective view showing two hollow bodies provided with anastomotic securing components constructed according to one embodiment of the invention,

the two bodies adapted to be joined via a side-to-side anastomosis;

Fig. 13 is a perspective view showing the two hollow bodies of Fig. 12 provided with anastomotic securing components constructed according to another embodiment of the invention;

5 Fig. 14A is a longitudinal sectional view taken through the side-to-side anastomosis formed according to the embodiment shown in Fig. 12;

Fig. 14B is a transverse sectional view taken through the side-to-side anastomosis formed according to the embodiment shown in Fig. 12;

Fig. 15 is a perspective view showing two hollow bodies provided with anastomotic securing components constructed according to one embodiment of the invention, the two bodies adapted to be joined via an end-to-end anastomosis;

Fig. 16 is a perspective view showing the two hollow bodies of Fig. 15 provided with anastomotic securing components constructed according to another embodiment of the invention;

15 Fig. 17A is a plan view of one of the hollow bodies and securing components shown in Fig. 12;

Fig. 17B is a longitudinal sectional view of the hollow body and securing component shown in Fig. 17A;

Fig. 18A is a plan view of the hollow body of Figs. 17A-17B and a securing component constructed according to an alternative embodiment of the invention;

Fig. 18B is a longitudinal sectional view of the hollow body and securing component shown in Figs. 18A;

Fig. 19A is a perspective view of the anastomotic securing component shown in Figs. 18A-18B, the component positioned in an opening in a hollow body with a lumen having a stenosis disposed proximal to the opening;

25 Figs. 19B-19C show anastomotic securing components constructed according to further alternative embodiments of the invention, the components being shown positioned in the hollow body of Fig. 19A;

Fig. 20A is a perspective view of a delivery device constructed to one embodiment of the invention, the device being shown in a first position;

Fig. 20B is a perspective view of the delivery device shown in Fig. 20A, the device being shown in a second position;

Fig. 21A is a perspective view of the delivery device shown in Fig. 20A with a

securing component constructed to one embodiment of the invention mounted thereon, the delivery device being shown in the first position;

Fig. 21B is a perspective view of the delivery device shown in Fig. 21A, wherein the device is shown in the second position as it is being manipulated to release the
5 securing component;

Figs. 22A-22F are sectional views schematically illustrating the delivery device shown in Figs. 20A-20B being used to deploy anastomotic securing components to form an end-to-side anastomosis according to one embodiment of the invention;

Fig. 23 is a perspective view of an exemplary application according to one
10 embodiment of the invention;

Fig. 23A is an enlarged view of a portion of the embodiment of Fig. 23 but showing a completed anastomosis;

Fig. 24 is a perspective view of another exemplary application according to another embodiment of the invention;

Fig. 24A is an enlarged view of a portion of the embodiment of Fig. 24 but showing a completed anastomosis;
15

Fig. 25 is a perspective view of an exemplary application according to still another embodiment of the invention;

Fig. 25A is an enlarged view of a portion of the embodiment of Fig. 25 but
20 showing a completed AV shunt with two anastomoses;

Figs. 26A-26B are exploded perspective views of a device constructed according to one embodiment of the invention for forming a magnetic port in a hollow body having a lumen;

Fig. 26C is an assembled perspective view of the device shown in Figs. 26A-
25 26B;

Fig. 26D is a sectional view taken along line D-D in Fig. 26C;

Figs. 27A-27B are sectional views illustrating alternative constructions of the device shown in Figs. 26A-26D;

Fig. 28 is an exploded perspective view of two devices which are constructed
30 according to another embodiment of the invention and are adapted to be coupled to tissue using magnetic force for forming a magnetic port in a hollow body having a lumen;

Fig. 29 is a sectional view taken through a vessel having a lumen, wherein the devices shown in Fig. 28 are coupled to the tissue of the vessel wall;

Fig. 30 is a sectional view of two magnets positioned in proximity to each other schematically illustrating the magnetic flux lines associated with the magnets;

Fig. 31 is a sectional view showing the two magnets of Fig. 30 provided with flux concentration mechanisms constructed according to another embodiment of the invention and schematically illustrating the magnetic flux lines associated with the magnets of the invention;

Fig. 32A is a perspective view of a device constructed according to another embodiment of the invention which is adapted to be coupled to tissue using electromagnetic force to form a magnetic port;

Fig. 32B is a perspective view of the device shown in Fig. 32A enclosed in a protective housing;

Fig. 33 is a perspective view of a device constructed according to yet another embodiment of the invention which is adapted to close an opening using electromagnetic force;

Fig. 34A is a sectional view taken through a target vessel having a lumen showing the device of Fig. 32B coupled thereto with a graft vessel shown (in phantom) prior to being anastomosed to the device;

Fig. 34B is a sectional view taken through a target vessel having a port defined by an anastomotic component communicating with the vessel lumen with the device of Fig. 33 positioned above the port prior to being used to close the opening;

Figs. 35A-35B are sequential sectional views taken through a target vessel having a lumen showing an anastomotic component constructed according to another embodiment of the invention being coupled to the wall of the vessel;

Figs. 36A-36B are, respectively, upper and lower perspective views of a device constructed according to another embodiment of the invention for forming a port in a vessel having a lumen, wherein the device has a mechanical attachment portion shown in a low profile or collapsed orientation;

Figs. 37A-37C are, respectively, upper plan, side elevation, and lower plan views of the device shown in Figs. 36A-36B;

Figs. 38A-38B are, respectively, upper and lower perspective views of the device shown in Figs. 36A-36B, wherein the mechanical attachment portion of the device is shown in a wide profile or expanded orientation;

Figs. 39A-39C are, respectively, upper plan, side elevation, and lower plan

views of the device as shown in Figs. 38A-38B;

Figs. 40A-40C are elevation views sequentially showing the device of Figs. 36A-39C being deployed in a vessel having a lumen;

Fig. 41A is a perspective view of a delivery device constructed according to another embodiment of the invention, wherein the device has a retaining portion shown in a first position to retain an anastomotic component;

Figs. 41B-41C are perspective views of the device shown in Fig. 41A but sequentially illustrating the retaining portion being moved to release the component;

Fig. 42A is a perspective view of a delivery device constructed according to still another embodiment of the invention, wherein the device has a retaining portion shown in a first position to retain an anastomotic component;

Figs. 42B-42C are perspective views of the device shown in Fig. 42A sequentially illustrating the retaining portion being moved to release the component;

Figs. 43A-43B are partial sectional views of the device shown in Figs. 42A-42C sequentially illustrating the device being used to couple an anastomotic component to a vessel;

Figs. 43C is a partial sectional view showing the anastomotic component in its final position;

Fig. 44 is a perspective view sequentially showing a flexible magnetic component constructed according to one embodiment of the invention being collapsed;

Figs. 45A-45B are perspective views illustrating a flexible magnetic component constructed according to one embodiment of the invention in its expanded and collapsed orientations, respectively.

Figs. 46A-46B shows alternative flexible magnetic components constructed according to additional embodiments of the invention;

Fig. 46C is a perspective view of a flexible component with a magnetic core constructed according to yet another embodiment of the invention, the component being adapted to substantially or completely close an opening in tissue or another component;

Fig. 46D is a perspective view of an alternative flexible magnetic component with a construction similar to the component of Fig. 46C but having an opening for placement in communication with the lumen of a vessel;

Fig. 46E schematically illustrates and exemplifies delivering the component shown in Fig. 46D in a low profile manner by way of a catheter or sheath;

Figs. 47A-47B are perspective views showing a device constructed according to another embodiment of the invention for closing openings in tissue in a restrained position for delivery and a partially deployed position, respectively;

Fig 47C is a fragmentary side elevation view of the device shown in Figs. 47A-47B but with the device fully deployed; and

Figs. 48A-48C are elevation views sequentially showing the device of Figs. 47A-47C being used to close a ventricular septal defect.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

One aspect of the present invention relates to methods and devices for forming an anastomosis between first and second (or additional) hollow bodies located in a patient's body, for example, a connection between a graft vessel and coronary or peripheral blood vessels, viscera, reproductive ducts, etc. The anastomosis places the hollow bodies, more specifically the lumens of the hollow bodies, in communication. In the case of blood-carrying bodies (or other hollow bodies that carry fluid) the anastomosis places the bodies in fluid communication. The hollow bodies being joined may comprise native or autologous vessels, vessels formed of synthetic material such as ePTFE or DACRON®.

Figs. 1-5 illustrate several exemplary embodiments of anastomotic securing components constructed according to the invention for use in forming an anastomosis between first and second hollow bodies. Fig. 1 shows a securing component 10 with an annular body and an opening 12 defined by the body. The component 10 is generally plate-shaped and circular in plan view with a constant (or substantially constant) thickness and width around its perimeter. The securing component 10 is sized and configured to be placed adjacent an opening of a first hollow body that has been prepared for anastomosis to a second hollow body. A second securing component would be placed adjacent an opening of the second hollow body for making the anastomotic connection.

Fig. 2 shows an elliptically-shaped, anastomotic securing component 14 with an opening 16. The securing component 14 is generally plate-shaped and the opening 16 is configured to provide the securing component 14 with larger end portions 18 than side portions 20. Fig. 3 shows a racetrack-shaped securing component 22 with an opening 24. As in securing component 14, the opening 24 provides securing component 22 with larger end portions 26 than side portions 28. Fig. 4 shows a securing component 30 with an opening 32, two end portions 34, 36 and two side portions 38. The securing component 30 has a generally

racetrack-shaped configuration, however, the end portion 36 is larger than the end portion 34 which provides the component 30 with an asymmetric configuration. Stated otherwise, the opening 32 is not centrally located with respect to the body of the component 30, unlike the openings 12, 16 and 24 of respective securing components 10, 14 and 22 shown in Figs. 1-3. Also, the end 36 provides a tapered leading edge for easier introduction into a hollow body such as blood vessel.

It will be understood that the specific shape and size of the securing components may be varied from the exemplary configurations depicted in Figs. 1-4. For example, the thickness or width of the securing component may vary along all or part of the body of the component. The anastomotic securing components of the invention are preferably, though not necessarily, plate-shaped, i.e., a first dimension D1 of the component is less than a second dimension D2 of the component (Fig 1). Typically, the lesser dimension corresponds to a thickness of the component while the larger dimension corresponds to a width or length of the component (or diameter in the case of Fig. 1). Minimizing the thickness of the securing component may be desirable for applications in which one or more components are placed within the lumen of a relatively small hollow body, e.g., a coronary artery, to reduce the amount of foreign material in the bloodstream and minimize flow impedance.

It will be noted that the securing components shown in Figs. 1-4 are generally flat; however, they could instead be curved or arcuate, or comprise a combination of flat and curved sections. Additionally, in the illustrated and preferred construction the shape of each securing component substantially corresponds to the opening therein. That is, the securing component and its opening preferably have complementary configurations (e.g., elliptical component, elliptical opening). Nevertheless, the securing component could have a non-complementarily-shaped opening. Finally, while each of the illustrated securing components includes only one opening, more than one opening could be used if desired.

According to preferred embodiments of the invention the anastomotic securing components are formed of or have incorporated therein a material capable of producing a magnetic field that acts to maintain the components in a desired positional relationship. The magnetic field results in the securing components maintaining the first and second hollow bodies in a desired position so as to be in fluid-tight communication. One or both securing components preferably has magnetic properties and may comprise permanent magnetic, ferro- or ferrimagnetic, or electromagnetic materials or assemblies.

Each of the securing components shown in Figs. 1-4 is formed substantially entirely of a suitable, magnetic field-producing material such that magnetic force may be generated over the entire area of the component. Fig. 5 shows an alternative embodiment wherein a securing component 40, which has an opening 42 and a racetrack-shaped configuration similar to securing component 22 of Fig. 3, has defined portions capable of producing a magnetic field. Specifically, the securing component 40 includes magnetic field-producing members 44 located at discrete areas which, in the illustrated embodiment, are at the ends of the component. The remaining areas 46 may thus be formed of a different material. It will be recognized that the members 44 could be located at alternative (or additional) areas of the securing component 40. An exemplary reason for providing the securing component 40 with areas 46 is to allow the use of a rigid magnetic material for the members 44 while still permitting the component to be partially or completely collapsed, for example, for delivery through a small incision or port, trocar, catheter, cannula, etc., by folding the areas 46.

Suitable materials that may be used to form an anastomotic securing component that is capable of producing a magnetic field include NdFeB (Neodymium Iron Boron), SmCo (Samarium Cobalt), and Alnico (Aluminum Nickel Cobalt). NdFeB is currently preferred for its force characteristics. The amount of force exerted will depend on various factors including the materials used, the size of the magnets and the number of magnets. In addition, different applications will call for different force ranges. For instance, it may be desirable to minimize the force as much as possible while still achieving a fluid-tight and secure attachment when treating small diameter blood vessels. As an example, in anastomosing coronary vessels, it is preferred to use anastomotic securing components that produce magnetic force in the area of less than 0.25 lbs, and more preferably approximately 0.15 lbs or less.

Figs. 6-8 depict first and second hollow bodies that have been prepared for anastomosis in three different manners. Fig. 6 shows a first hollow body 50 with an opening 52 that is adapted to be joined to an opening 54 of a second hollow body 56 to form an end-to-side anastomosis. The completed anastomosis places the lumens of the respective hollow bodies in communication. The opening 52 is formed in the wall of the first hollow body 50, for example, by incising or punching the tissue of the wall, while the opening 54 is defined by an end of the second hollow body 56. Fig. 7 shows a first hollow body 58 with an opening 60 adapted to be joined to an opening 62 of a second hollow body 64, thereby forming a side-to-

side anastomosis that places their lumens in communication. The openings 60, 62 are formed in the walls of the hollow bodies 58, 64, for example, as described above regarding opening 52. Fig. 8 shows a first hollow body 66 with an opening 68 adapted to be joined to an opening 70 of a second hollow body 72 to form an end-to-side anastomosis. Each opening 68, 70 is defined by an end its associated hollow body 66, 72.

Figs. 9 and 9A show first and second hollow bodies 74, 76 respectively provided with first and second anastomotic securing components 78, 80 which are used to create an exemplary end-to-side anastomosis according to one embodiment of the invention. As shown best in Fig. 9A, the securing component 78 includes two members 78A, 78B disposed on opposite surfaces of a wall of the first hollow body 74. The securing component 80 includes two members 80A, 80B disposed on opposite surfaces of an everted end of the second hollow body 76. The members forming each securing component 76, 78 may be held in a desired and preferably fixed relative position by magnetic force, with magnetic force also being used to hold the two securing components in position. The securing components 78, 80 are moved together from the position of Fig. 9A to create a fluid-tight anastomosis.

Figs. 10A-10D depict additional end-to-side anastomoses formed according to other embodiments of the invention. Fig. 10A shows a first securing component 82 coupled to a first hollow body 84 and a second securing component 86 coupled to a second hollow body 88. The securing components 82, 86 have a laminated structure comprising one layer of material capable of producing a magnetic field disposed between two outer layers of different material. In order to produce a magnetic field the components may comprise, for example, permanent magnetic, ferromagnetic, ferrimagnetic or electromagnetic materials or assemblies. Some exemplary materials that may be used include metals, polymers, ceramics, etc.

One example of this embodiment of the invention comprises a securing component having a middle layer of permanent magnetic material (e.g., NdFeB) and two outer layers of ferromagnetic material (e.g., 300 or 400 series stainless steel). The outer layers may be attached to the middle layer by suitable adhesive or magnetic force. One specific example of a securing component constructed according to this embodiment comprises a 0.008" thick inner magnetic layer and two 0.001" thick outer stainless steel layers. It will be understood that this aspect of the invention may be practiced using other materials or assemblies.

A benefit of a laminated construction is that it allows the thickness of the magnetic layer to be reduced because the other layer(s) will provide the assembly with the

necessary strength and integrity, even if the magnetic layer is very thin (which typically makes the brittle magnet more easily fractured). In the above example, the steel layers may be very thin yet still able to absorb the load, e.g., the tensile forces that arise during movement of the hollow body or adjacent tissue. The particular overall dimensions of the securing component, as well as the dimensions of individual layer (or layers if a multilayer construction is used) will of course depend on the application. (As examples, for the securing component 22 shown in Fig. 3, the thickness is preferably less than 0.040", and more preferably less than 0.020", e.g., approximately 0.015" or even less, e.g., 0.008".)

The ability to form a very thin securing component allows formation of an anastomosis between relatively small hollow bodies, e.g., coronary blood vessels. Further, the anastomosis can be formed between blood-carrying hollow bodies with one or more of the securing components located in the blood flow path while minimizing the foreign material exposed to blood.

Fig. 10B shows first and second securing components 90, 92 coupled to first and second hollow bodies 94, 96. The first securing component 90 comprises a single member 98 positioned within the lumen of the first hollow body 94 against the interior surface of the wall of the body adjacent an opening therein. The member 98 has a coating 100 substantially, and preferably completely, surrounding its exterior surface. It may be desirable in some applications to apply a suitable coating, or alternatively, a suitable surface treatment, to all or part of the anastomotic securing component. For example, if the first hollow body 94 represents a blood vessel such as a coronary or peripheral artery, the securing component 90 will be exposed to the blood flow path. As such, depending on the material used to form the member 98, it may be desirable or necessary to coat or otherwise treat its surface to promote better thrombogenicity and/or improve flow past the anastomosis site. Some exemplary materials that may be used to coat or otherwise treat an anastomotic securing component constructed according to the invention include Gold, Platinum, Titanium Nitride, Parylene, Silicone, Urethane, Epoxy, Teflon and Polypropylene.

Fig. 10C shows an embodiment wherein first and second securing components 102, 104 are coupled to first and second hollow bodies 106, 108. Each component 102, 104 comprises a single member formed, as explained above, of a magnetic, ferromagnetic, or electromagnetic material. This embodiment, instead of everting an end of one of the hollow bodies 106, 108, provides the first securing component 102 with a portion 110 configured to attach the end of the first hollow body 106. The portion 110 may take various forms, for

example, a DACRON® suture ring or bioadhesive. It will be recognized that the portion for attaching the hollow body may be located at different areas of the second securing component 104 than shown in Fig. 10C.

Fig. 10D shows an embodiment of the invention similar to that of Fig. 10C with first and second securing components 112, 114 coupled to first and second hollow bodies 116, 118. The means for attaching the first securing component 112 to the first hollow body 116 in this embodiment comprises an expandable member 120, such as a stent, disposed within the lumen of the first hollow body. The member 120 forces the end of the first hollow body 116 against the first securing component 112 to attach the elements in a fluid-tight fashion. It will be appreciated that the embodiments of Figs. 10C and 10D are only two of the various ways in which a securing component may be coupled to a hollow body with everting tissue of the hollow body.

Fig. 11A is a transverse sectional view taken through an end-to-side anastomosis created by first and second securing components 122, 124 which are positioned adjacent openings of first and second hollow bodies 126, 128. The securing components 122, 124 are plate-shaped (as described above) and generally flat. Fig. 11B shows first and second securing components 130, 132 constructed according to an alternative embodiment of the invention positioned adjacent the openings of first and second hollow bodies 126, 128. The securing components 130, 132 are also plate-shaped but, rather than being generally flat, are arcuate or curved. As can be seen, the curvature of the securing components 130, 132 maintains the first hollow body 126 in a substantially round configuration as compared to the more flattened-out shape it assumes when used with the flat securing components 122, 124.

The arcuate securing components 130, 132 preferably have complementarily or substantially complementarily radii of curvature to provide an even distribution of force and good sealing. The securing components of the invention could, however, have different degrees of curvature, the curvature of each being either constant or changing over the body of the component. Also, while the illustrated securing components 130, 132 extend over approximately 120°, other configurations that extend between 0° and 360° could be used if desired, for example, 180°. Finally, while Figs. 11A and 11B show, respectively, a pair of flat components and a pair of arcuate components, the securing components of each pair used to create the anastomosis may have dissimilar configurations to varying degrees.

Figs. 12 and 13 show other embodiments of the invention wherein first and second hollow bodies 134, 136 are respectively provided with securing components in order

to create an end-to-side anastomosis. The embodiment of Fig. 12 utilizes first and second securing components 138, 140 respectively positioned adjacent openings in the hollow bodies 134, 136. Each securing component 134, 136 includes a single member that may comprise one or more materials and one or more layers, as described above. The components may be
5 fixed by adhesive or other means or remain in position via magnetic force, as explained above. The securing components 138, 140 are positioned through openings formed in the wall of the hollow bodies 134, 136 and are located within the respective lumens L1, L2 thereof, as shown in Figs. 14A and 14B. Once joined the components 138, 140 form a fluid-tight anastomosis that places the first and second hollow bodies 134, 136 in communication.
10 If the hollow bodies 134, 136 are blood (or other fluid) carrying structures, the anastomosis places them in fluid communication and provides a fluid-tight seal.

The embodiment of Fig. 13 uses first and second securing components 142, 144 which are respectively positioned adjacent openings in the hollow bodies 134, 136 so as to be partially disposed within the lumens thereof. The opening in each hollow body may be
15 formed by making a surgical incision, removing tissue with a punch, etc. Each securing component 142, 144 includes a pair of members, and each member may comprise one or more materials and one or more layers. One member of each securing component 142, 144 is positioned within the lumen of its hollow body while the other member of the securing component is positioned on the exterior of the hollow body with tissue in between.

20 Figs. 15 and 16 show further embodiments of the invention wherein first and second hollow bodies 146, 148 are respectively provided with first and second anastomotic securing components in order to create an end-to-end anastomosis. Fig. 15 shows first and second securing components 150, 152 positioned adjacent respective openings of the hollow bodies 146, 148, each opening being defined by an end of a hollow body and extending into
25 the lumen thereof.

Each securing component 150, 152 includes a single member that may be constructed as described above. An end of each hollow body 146, 148 is passed through the opening defined in by a respective securing component and then is everted over the exterior of the component. As a result, joining the first and second securing components 150, 152 in
30 end-to-end fashion places the everted ends of the hollow bodies 146, 148 in sealed contact. In a case where the hollow bodies are natural blood vessels, such an anastomosis places the intimal surfaces of the vessels in contact.

The embodiment of Fig. 16 includes first and second securing components

154, 156 positioned adjacent the openings of hollow bodies 146, 148, respectively. The securing components 154, 156 each comprise a pair of members constructed as described above. The first securing component 154 includes one member 154A positioned around the exterior of the first hollow body 146 (with the end thereof everted), and another member
5 154B positioned around the opening defined by the end of the hollow body 146, the members 154A, 154B being held in place by magnetic force. The second securing component 156 has the same or a similar construction and includes members 156A, 156B which are positioned adjacent the end of the second hollow body 148. In the embodiments of Figs. 15-16 the securing components are not located within the lumen of either hollow body and thus are not
10 exposed to fluid or other substances contained therein or moving therethrough.

Another embodiment of the invention will be described with reference to Figs. 17A-17B. Fig. 17A shows a hollow body 160 with an opening 162 and an anastomotic securing component 164 positioned adjacent the opening. The securing component 164 is positioned within the lumen L of the hollow body 160 and has an opening 166. The opening
15 166 is aligned with the opening 162 in the wall of the body 160 as shown. In some instances, for example, when the securing component is forced through an incision in the wall, the tissue defining the opening 162 may move over the opening 166 of the securing component 164, as shown in Fig. 17B. As indicated by reference numeral 168 in Fig. 17B, this reduces the effective area of the securing component 164 that is available to communicate with a
20 second hollow body to which the hollow body 160 is anastomosed (not shown).

Fig. 18A-18B show the hollow body 160 with the opening 162 of Figs. 17A-17B, however, a securing component 170 constructed according to another embodiment of the invention is positioned adjacent the opening 162. The securing component 170 has an opening 172 and has a feature for maintaining the opening 162 open to flow. The securing
25 component 170 comprises a flange 174 and an extension 176 coupled thereto (or formed integrally therewith). As can be seen, the extension 174 prevents tissue defining or adjacent the opening 162 of hollow body 160 from migrating or springing back after delivery to reduce the cross-sectional flow area of the securing component 170.

Figs. 19A-19C show a hollow body 180 which may, for example, represent a
30 patient's coronary or peripheral artery the lumen of which is stenosed at S. In Fig. 19A, the hollow body 180 is provided with the anastomotic securing component 170 of Figs. 18A-18B by coupling the securing component to an opening in the wall of the artery, thereby forming a site for creating an end-to-side or side-to-side anastomosis. In Fig. 19B, the hollow body 180

is provided with an alternatively configured anastomotic securing component 182 which includes a flange 184 and a discontinuous or segmented extension 186 passing all or partly through the opening in the wall of the hollow body. Fig. 19C shows a securing component 188 with a multi-part construction including a flange 190 and a separate extension 192 which is received in the opening of the hollow body 180. It should be understood that these are only a few of the various constructions that may be employed in practicing this aspect of the invention.

The anastomotic securing components of the invention may be delivered and deployed in various ways. Figs. 20A-20B and 21A-21B depict somewhat schematically an exemplary delivery device 200 including a first portion 202 operatively coupled to a second portion 204. The first portion 202 is fixed to a shaft 206 while the second portion 204 is fixed to shaft 208 passing through a slot 210 in the portion 202. The first portion 202 defines a support ledge 212 and the second portion 202 similarly defines a support ledge 214. Fig. 20A shows the device 200 in a first position for retaining an anastomotic securing component of the invention. This position is shown in Fig. 21A wherein the ledges 212, 214 support a securing component 216 with the opening 218 of the component surrounding a boss 220 that extends upwardly from the ledges. The boss 220 is preferably used to help align the securing component on the support ledges 212, 214 and, if used in an application with an opening formed in a side wall of a hollow body, to restrain the surrounding tissue during placement.

Figs. 20B and 21B show the device 200 after it has been moved to a second position from the position of Figs. 20A and 21A. This is achieved by moving the shaft 208 in the direction of the arrows to slide the second portion 204 with respect to the first portion 202, which moves the support ledge 214 within the opening 218 of the anastomotic securing component 216 (Fig. 21B). This allows the user to separate the device 200 from the securing component 216 once the latter has been positioned at the desired location. As shown, depending on the relative dimensions and shapes of the respective components it may be necessary to rock or otherwise manipulate the device 200 relative to the securing component 216 in order to separate them.

It will be understood that the illustrated delivery device 200 is only one possible device suitable for use in placing the anastomotic securing components of the invention, and that it may be modified or replaced with a different delivery device or system. For example, the delivery device 200 could be altered so that both support ledges 212, 214 are moved with respect to the boss 220 (if used) in order to move fully out of contact with and

release the securing component. Any suitable material(s) may be used to construct the delivery device 200, it being appreciated using magnetic or ferromagnetic materials may result in magnetic interaction with the securing components, which may be desired to facilitate delivery of the components. The delivery device could also be constructed of nonmagnetic or ferromagnetic materials such as titanium, polymers, etc.

For sake of example, the creation of an anastomosis using the delivery device 200 and first and second securing components of the invention will be described with respect to Figs. 22A-22F. Fig. 22A shows the delivery device 200 with a first securing component 222 comprising two members 222A, 222B, the former member being supported by the ledges 212, 214 of the device 200 while the latter member is held above the ledges (e.g., by magnetic attraction to the device 200). The member 222A is being inserted into an opening in the wall of a blood vessel V with a stenosis S. The member 222A may be shaped or otherwise treated to ease insertion into the vessel lumen; for example, the leading edge of the member 222A may be formed as shown in the embodiment of Fig. 5.

Fig. 22B shows the one member 222A of securing component 222 positioned against the interior surface of the wall of the vessel and the other member 222B being moved toward the vessel wall. Fig. 22C shows the members 222A, 222B in position with the delivery device 200 remaining. Fig. 22D shows the device 200 being removed through first securing component 222, and Fig. 22E shows the securing component 222 remaining in the vessel wall to form what may be characterized as a magnetic port P. The securing component(s) may be provided with a surface treatment, such as coatings, roughened or treated areas, or mechanical projections, to enhance engagement with the wall of the hollow body.

The illustrated securing component 222 defines the magnetic port P and produces a magnetic field that may be used to couple another vessel to the port. In Fig. 22F, a graft vessel G provided with a second securing component 224 (which itself includes two members) is anastomosed to the port P with magnetic force holding the first and second securing components 222, 224 in a desired relative position. The invention may also be practiced using means for fixing the relative distance between the first and second securing components, for example, to prevent tissue being forced or squeezed from the space between the components due to the application of the magnetic force over time. Such means could comprise projections that extend directly between the components and act as a stop, or an intermediate element coupled to the components to restrain them against further movement.

It will be recognized that forming a magnetic port according to the invention may also be used in non-vascular applications, as well as applications not requiring an anastomosis to another vessel, for example, to provide an access to an area of a patient's body.

Several exemplary applications of the invention will be described with reference to Figs. 23-23A, 24-24A and 23-25A. Fig. 23 is an anterior view of a human heart with a graft vessel G having one end 230 attached to the aorta, e.g., by a sutured anastomosis, and another end 232 prepared to be anastomosed to an occluded LAD. One securing component 234 is coupled to the end 232 of the graft G by any of the methods described above, and another securing component 236 is coupled to the LAD adjacent an opening therein. The securing components 234, 236 are formed (at least in part) of materials capable of producing a magnetic field so that they may be attached as shown in Fig. 23A, thereby placing the graft G in fluid communication with the lumen of the LAD. The graft G could alternatively be attached to the aorta by an anastomotic system constructed according to the invention.

Fig. 24 shows another exemplary application of the invention applied to the heart shown in Fig. 23. A ventriculocoronary shunt S has one end 237 placed in the myocardium in fluid communication with the left ventricle LV. The shunt S is provided with a securing component 238 adjacent its other end while the LAD is provided with the securing component 236 of Fig 23. The shunt S is adapted to be coupled to the LAD via a side-to-side anastomosis, therefore the securing component 238 is positioned in an opening in the side wall of the shunt (and the free end of the shunt is tied off at 240). Fig. 24A shows the completed anastomosis once the securing components 236, 238 have been coupled and remain in position via the magnetic field produced according to the teachings of the invention.

Figs. 25-25A illustrate yet another example of the many different applications of the invention, namely, the creation of an AV shunt. Fig. 25 shows a patient's arm including a number of the blood vessels located therein. An artery 242 is shown disposed in relatively close proximity to a vein 244. AV shunts are often created between an artery and vein in order to provide a site for repeatedly accessing a patient's vascular system, for example, to treat dialysis patients. The shunt itself is typically formed of synthetic graft material and can withstand repeated needle sticks much better than a natural vein. An AV shunt 246 is created between the artery 242 and vein 244 by forming a side-to-side anastomosis using first and second securing components 248, 250. The shunt 246 is

preferably formed of ePTFE, DACRON® or another suitable synthetic graft material.

It should be appreciated that the applications of Figs. 23-23A, 24-24A and 23-25A represent several of many different uses for the invention. Other applications for the invention include, for example, neurological, urological and gastrointestinal procedures. As a further example, the invention could be used to form an anastomosis with an existing CABG graft that has partially or completely occluded over time, for instance, by placing the anastomotic securing components in the graft distal to the occlusion. In short, it will be recognized that the invention may be modified in varying degrees from the preferred embodiments illustrated and described specifically herein.

As noted above, it will be recognized that the invention may be used in many different procedures, for example, femoral-femoral, femoral-popliteal, femoral-tibial, ilio-femoral, axillary-femoral, subclavian-femoral, aortic-bifemoral, aorto-iliac, aorto-profunda femoris and extra-anatomic bypasses. In sum, the invention may be used to create an anastomosis with many different vessels, including, without limitation, the renal arteries, mesenteric vessel, inferior mesenteric artery, eroneal trunk, peroneal and tibial arteries.

Another embodiment of the invention will be described with respect to Figs. 26A-26D. A device for forming a port into a vessel (or for forming part of an anastomotic coupling) is indicated generally by the reference numeral 252 in Fig. 26A. The device 252 includes a member capable of producing a magnetic field, for example, permanent magnet 254, which preferably has an opening 256 adapted to communicate with a vessel lumen or other hollow body. The magnet 254 is received in a housing that, in this embodiment, comprises two elements configured for attachment to each other so as to enclose the magnet. One housing element 258 is generally dish-shaped with a rim 260 while the other housing element 262 is generally lid-shaped (as seen in Fig 26A).

Fig. 26B shows the magnetic member 254 disposed in the element 258 with the element 262 positioned above the assembly. Fig. 26C shows the element 262 affixed to the element 254 to form the housing and provide a sealed enclosure containing the magnetic member 254. This enclosure preferably forms a hermetically sealed environment that will protect the member 254 from external elements, e.g., blood or various bodily fluids, upon implanting the device 252 in a patient. The illustrated housing elements 258, 262 may be attached by any suitable means. For example, if constructed of metal laser welding may be used to join the housing elements. Other attachment means include adhesives, fasteners, etc.

The housing enclosing the magnetic member may of course be formed of a

unitary piece of suitable material, for example a metallic blank, or more than two pieces of material joined as described above. Fig. 26D is a sectional view of the device 252 shown in Fig. 26C illustrating the internal construction of the device, with lid element 262 resting on and secured to the rim 260 of dish element. Fig. 27A shows an alternative construction wherein the member 254 is enclosed in a housing defined by a spool-shaped element 264 and a pair of lid-shaped elements 266 secured thereto, for example as described above. Fig. 27B shows yet another construction wherein the member 254 is enclosed in a housing defined by mating channel-shaped elements 268, 270 which are secured together to form the enclosure for the member 254. The housing enclosing the magnetic member is preferably formed of a material that is a good to excellent conductor of magnetic flux. Exemplary materials are discussed above with respect to Figs. 26A-26C, as well as below in connection with Figs. 28-31.

Fig. 26C also shows (in phantom) a schematic representation of means for indicating the polarity of the magnetic member 254. The illustrated indicator 272 may take the form of any suitable writing, color, etc., to indicate the polarity of the magnetic field produced by the member 254. For example, the indicator 272 may simply comprise the printed letters "N" or "S." This feature allows a user to confirm proper orientation of the device 252 relative to another device, thereby ensuring that the devices will attract each other (or repel each other, if that is desired). Other possible ways of ensuring proper orientation include pre-mounting the component(s) on a delivery instrument in a selected position, or providing a mechanism that automatically orients the component in the selected position. It may also be desirable to allow the component to be removed and remounted on the delivery device if its orientation is incorrect.

Turning to Figs. 28-31, another embodiment of the invention will be described and includes methods and devices for increasing the magnetic attracting force between two components. Fig. 28 shows first and second components 274, 276 adapted to be coupled to a target vessel via magnetic attraction. The first and second components 274, 276 comprise, respectively, members 278, 280 which are capable of producing a magnetic field, as well as mechanisms 282, 284 for increasing the magnetic attraction force between the components. That is, when provided with the mechanisms 282, 284 and placed in proximity the components 274, 276 produce a higher magnetic force than when placed in proximity without the mechanisms.

Fig. 29 shows the components 274, 276 positioned on opposite surfaces of the

wall W of a target vessel TV and coupled thereto by magnetic force. As shown, in order to form a port that communicates with the vessel lumen L, which is partially occluded at O, the components may have openings, such as respective openings 286, 288 in components 274, 276. These openings preferably are aligned with complementary openings in the mechanisms 282, 284 to form a port extending into the lumen. The mechanisms 282, 284 enhance the magnetic attraction between the components 274, 276, thereby more securely attaching the assembly to the vessel wall W than if the mechanisms were omitted.

Referring to Figs. 30-31, the concept underlying this aspect of the invention will be described with respect to the specific embodiment of Figs. 28-29. Fig. 30 shows the first and second members 278, 280 (which may be viewed as a pair of permanent bar magnets) in relatively close proximity, the poles of the magnetic members being oriented so that the components attract each other. Fig 30 also schematically depicts the magnetic field produced by the magnetic members 278, 280. The magnetic field F1 located between the members 278, 280 is essentially uniform given the relatively large surface areas of and the small separation gap between the members. The number of lines present between the members 278, 280 is roughly indicative of the strength of field F1.

As shown, the magnetic field F2 located at the edges of the members 278, 280 fringes out, which dissipates or weakens the field F2. The field F2 fails to significantly increase the attraction force between the members 278, 280 due to its location and the fact that it is relatively weak (as it contains fewer, more spaced apart flux lines than the field F1). Put another way, the magnetic flux density or magnetic induction B (which is a measure of magnetic field strength) of field F1 is greater than the magnetic flux density of field F2. The invention provides means for utilizing the field F2 to increase the magnetic attraction force between two components. It will be noted that for sake of clarity Fig. 30 omits the portion of the magnetic field that would extend inward toward the center of each component.

Fig. 31 shows the members 278, 280 along with the mechanisms 282, 284 in fairly close proximity. The magnetic field F1 located between the members 278, 280 is essentially uniform as described above in connection with Fig. 30. As can be seen, though, the mechanisms 282, 284 alter the location and flux density of the magnetic field F2. Specifically, rather than fringing out as in Fig. 30, the field F2 is concentrated by the mechanisms 282, 284 between the components 274, 276. As such, the magnetic flux density increases, which in turn increases the attracting force between the components.

The specific manner of increasing the magnetic attraction force may vary from

that shown. The illustrated mechanisms 282, 284 are configured to alter the construction of the magnetic members 278, 280 in order to increase magnetic flux density and hence raise the attraction force produced thereby. The mechanisms 282, 284 are separate elements coupled to the members 278, 280; however, means for increasing the magnetic force may comprise an
5 integral portion of the magnetic member, a layer or coating applied to the member, etc. Further, the preferred mechanisms are channel-shaped to form an extension of the magnetic member that effectively channels the magnetic field F2 and concentrates the magnetic flux between the components 274, 276 (and more specifically, between the confronting edges of the mechanisms 282, 284). It will, however, be appreciated that this aspect of the invention
10 may be practiced using mechanisms having alternative configurations.

The mechanisms 282, 284 have a magnetic permeability higher than air in order to concentrate the magnetic flux and increase the magnetic flux density and attracting force. That is, the mechanisms provide a path of least resistance as compared to air so that the magnetic flux flows into the mechanisms rather than the air. This in effect forms a
15 magnetic circuit that captures a significant amount of the magnetic field F2 that otherwise would not contribute to the attracting force between the two components. One benefit of this aspect of the invention is that it allows a thinner magnetic member to be used for the component without sacrificing (or even increasing) magnetic field strength. In some applications, such as creating anastomoses on small vessels, it is typically desirable (e.g., for
20 thrombogenicity reasons) to minimize the amount of foreign material located within or against the vascular tissue.

The material used to form the mechanism for increasing magnetic force preferably has a high magnetic permeability μ in order to concentrate a desired amount of magnetic flux in one or more desired areas. The mechanism is preferably formed of
25 ferromagnetic material having a μ that is greater than the μ of air. More preferably, the material has a μ that is greater than 1.0, and even more preferably, significantly greater than 1.0 or as high as possible. Exemplary ranges of μ values include from about 1.0 to about 250,000, and from about 1.0 to about 1000. While ferromagnetic materials are preferably used to form the flux concentration mechanisms, other materials may be used instead. For
30 example, ferrimagnetic, paramagnetic or diamagnetic materials may be used (although the results they achieve may be inferior to those obtained using a ferromagnetic material).

Tests have shown that, depending on the size, material and separation gap of the respective components having magnetic properties, the flux concentration mechanisms of

the invention may be used to produce a magnetic attraction force that is from about 5 % to about 75 % higher than that obtained without flux concentration mechanisms. More preferable, though, is a flux concentration mechanism that increases the force from about 20 % to about 75 %. The exact amount of magnetic force used in practicing the invention, for example, to secure the components to a vessel, will depend on various factors, such as the sized of the vessel, the force limit prior to causing necrosis, etc.

It will be apparent that this feature of the invention provides ample benefits including a firm attachment to tissue via magnetic force, the ability to alter the construction of a component to customize the amount or location of flux concentration, and the ability to reduce the size of the magnetic component while maintaining sufficient magnetic force to form the anastomosis.

Figs. 32A-32B show an anastomotic component 286 in the form of an electromagnet assembly including a core 288 having an opening 290. A coil 292 is wrapped around the sidewall of the core 288 and has leads 294 running to a power source, such as battery 296 (Fig. 32B). Fig. 32B shows the component 286 after it has been placed in a protective housing 298 by suitable means, for example, a coating or structural enclosure as described above. The housing 296 is preferably formed of a strong, leak-tight biocompatible material.

Fig. 33 shows an electromagnetic component 300 for use in closing an opening, for example, an opening in tissue such as an ASD, VSD, PDA, etc. As can be seen the component 300 includes a housing 302 with at least one occlusion surface 304 adapted to seal against tissue or an anastomotic component.

Fig. 34A is an example of the component 286 coupled to an anastomotic component 286A positioned on the opposite surface of the of a target vessel TV with a lumen L. A graft vessel G is shown (in phantom) just above the component 286 and includes an anastomotic component AC oriented to magnetically attract (or be attracted to) the electromagnetic assembly of component 286. Fig. 34B shows the occluding surface 304 of component 300 being used to close, either temporarily or permanently, a magnetic port P which communicates with the lumen L of the target vessel TV.

The invention may be practiced using magnetic, mechanical, or any other force-creating means to secure a component to tissue or to another component. Fig. 35A shows two anastomotic components 304, 306 including first and second magnetic members 308, 310 enclosed in housings 312, 314. The first component 304 has a sleeve portion 316

(which in Fig. 35A is an extension of the housing 314) having an end 318 that projects beyond the second component 306. Any suitable means may be used to collapse or other manipulate the end 318 relative housing 314 of second component 306, for example, the instrument represented schematically in Fig. 35A. As shown in Fig. 35B, the instrument is
5 moved in the direction of the arrows to collapse the end 318 and mechanically couple the securing components 304, 206. As a result, this embodiment joins the components by both magnetic and mechanical forces.

Figs. 36A-39C show another embodiment in the form of a component 320 to be coupled to tissue by a mechanical attachment portion 322. The component 320 includes a
10 base 324 and a member 326 for producing a magnetic field. An opening 328 passes through the component 320 and is placed in communication with a target vessel, for example, a coronary or peripheral artery. Figs. 36A-36B and 37A-37C show the component 320 in a low profile or collapsed configuration for delivery. The illustrated attachment portion 322 includes a plurality of arms 330 adapted to engage tissue of the target vessel wall, which
15 results in the vessel wall being sandwiched between the ends 332 of the arms 330 and the base 324. The component 320 may comprise separate members, as in the illustrated embodiment, or it may comprise an integral structure with or without a magnetic portion.

Figs. 38A-38B and 39A-39C show the component 320 in a raised profile or expanded configuration corresponding to its deployed, tissue-engaging position. Fig. 39B
20 shows (in phantom) tissue T engaged by the expanded arm 332. These Figures show, however, an optional feature of this embodiment, namely, a biocompatible layer G adapted to be placed in contact with the tissue. Exemplary uses for such as layer, which may be formed of any suitable material, include sealing the vessel opening and promoting tissue ingrowth at the site. This embodiment of the invention uses mechanical force to couple a component to
25 the tissue but forms a magnetic port (via member 326) that may be anastomosed to another component having the same or a different construction. It will be recognized that the component 320, rather than presenting a magnetic port for docking a vessel, could present an alternative structure for attaching a graft, such as a stent, staples or fasteners, adhesive, etc.

Figs. 40A-40C shows an exemplary use of the device illustrated in Figs. 36A-
30 39C. A delivery device 334 is schematically shown and includes a tip 336 which is preferably configured to incise and dilate tissue. The tip 336 may be mounted on a shaft 338 and has a recess that receives the ends 332 of the arms 330 (Fig. 40A) and retains them in their collapsed configuration. The delivery device 334 also has an end 340 for contacting the

magnetic member 326 of the component 320 to prevent movement of the arms 330 relative to the delivery device.

Fig. 40A shows the device 334 after the tip 336 has cut through tissue of a vessel wall W and the component has been properly positioned against the surface of the wall.

5 Fig. 40B shows the device 334 after the shaft 338 has been moved distally to release the ends 332 of component arms 330 and allow them to expand into contact with the tissue T. Next, as shown in Fig. 40C, the delivery device 334 with shaft 338 is removed proximally through the opening 328 of component 320.

It will of course be appreciated that this embodiment of the invention may take
10 many constructions other than those specifically illustrated herein. For example, rather than having individual arms 330 which engage the tissue T, a continuous or semi-continuous surface could be used, the surface being planar, concave-convex, etc.

Figs. 41A-41C show a delivery device constructed according to yet another embodiment of the invention. The delivery device 342 includes a support portion 344 and a
15 retaining portion or mechanism 346 for retaining a securing component SC on the device. The illustrated retaining portion 346 is carried by a shaft 348 and engages a flange 350 formed on (or attached to) the securing component SC around its opening 352. The flanged securing component SC is preferably magnetic and may be constructed as described above regarding previous embodiments (e.g., Figs. 19A-19C). Fig. 41A shows the delivery device
20 342 in a first position in which the retaining portion 346 is in its first position to retain the securing component SC. It will be noted that the device 342 may also be used to deliver a non-flanged securing component(s).

Fig. 41B shows the delivery device 342 after the retaining portion 346 has been moved out of the first position to release the securing component 342. In this
25 embodiment the retaining portion is rotated 90° from the first position, although other motions may be used to release and engage the securing component. Fig. 41C shows the delivery device 342 after it has been withdrawn proximally through the opening 352 in the securing component 342. Fig. 41C also shows the particular construction of the support portion 344 of device 342. A step 354 is formed to receive the opening 352 of the securing
30 component 342. The step 354 helps align the securing component and aids in even delivery to the tissue surface.

Figs. 42A-42C show a delivery device 356 constructed according yet another embodiment of the invention. The device 356 includes a body 358 which to some extent acts

as a support portion for first and second components 360, 362. A first retaining portion or mechanism 364 is movable relative the body 358 and engages the first component 360 to retain it in place prior to and during delivery. A second retaining portion or mechanism 366 is also movable and engages the second component 362 to retain it in place. A shaft 368 supports the first retaining portion 364, and the body 358 has a notch 370 which facilitates introducing the components into a vessel lumen, as described below.

Fig. 42B shows the device 356 after the second retaining portion 366 has been moved toward first component 360 to drive the second component 362 to its desired position, for example, against an opposite surface of the vessel wall. Fig. 42C shows the device 356 after the first retaining portion 364 has been moved distally relative to the body 358 of the device. The portion 364 is wedge-shaped and this motion moves the portion 364 out of contact with the first component 360, thereby releasing it from the device. Magnetic attraction maintains the two components 360, 362 in place.

Figs. 43A-43C show the delivery device 356 being used to couple the first and second components 360, 362 to a vessel wall W. As shown in Fig. 43A, the notch 370 can be used to guide the first component 360 through an incision in the wall W. It should be noted now that another aspect of this embodiment provides an offset structure for easier introduction of the leading end of a component. As can be seen in Fig. 43A, this feature allows the longer component 360 to be introduced through a shorter incision. The term offset means that the body 358, i.e., the delivery end of the device 356, extends laterally in one direction to give the device an asymmetrical configuration. For example, in the illustrated embodiment the body 358 extends to one side and defines the notch 370, but does not extend laterally in the opposite direction. Put another way, the delivery end of the device 356 is offset with respect to a longitudinal axis of the device.

Fig. 43B show the first component 360 passed through the incision and the second component 362 being lowered to a position that achieves the desired amount of magnetic attracting force. Fig. 43C shows the resulting position of the two components with their openings generally aligned with the incision in the wall W.

As mentioned above with respect to Fig. 5, the invention may be practiced using flexible components that are capable of producing a magnetic field. Fig. 44 shows another embodiment comprising a component 374 in the form of a foldable sheet being collapsed, for example, in order to deliver the component percutaneously. Figs. 45A-45B show, respectively, expanded and collapsed orientations of a component 376 constructed

according to another embodiment. Figs. 46A-46B show, respectively, components 378, 380 having magnets 382 disposed partially therein so as to allow at least partial collapsing of the components in accordance with yet another embodiment.

Fig. 46C shows a component 384 constructed according to another
5 embodiment in its expanded state. A frame 386 supports a web or body 388 and is capable of producing a magnetic field while being collapsible for easier delivery. The web 388 may be used to occlude an opening. Fig. 46D shows a collapsible component 390 that may be used to form a magnetic port or an anastomosis. The component 390 preferably comprises a magnetic core covered by a superelastic or shape memory housing and has ends 392 that
10 permit the component to be delivered in a straight, low-profile configuration. Fig. 46E shows an exemplary catheter C retaining the component 390 in a low-profile orientation.

Figs. 47A-47C show yet another embodiment of the invention that provides a device 394 for closing an opening in tissue, such as any of the cardiovascular defects mentioned above. The device 394 could be used in other applications as well. In Fig. 47A a
15 sheath or catheter 396 houses a pair of magnetic components 398, 400 on a shaft 402. The components 398, 400 may take any of the previously described constructions and are configured to attract each other across a body of tissue with an opening to be closed. Fig. 47B shows the device 394 after relative movement has been imparted to the sheath 396 and the components 398, 400. The component 398 is out of the sheath 396 and fully expanded while the component 400 is partially out of the sheath and expanded. Fig. 47C shows the
20 device 394 with the component 398 exploded from the shaft 402. The shaft 402 and component 398 have mating magnetic and/or mechanical interlocking means indicated at 404, such means securely holding the component 398 during delivery and then releasing it preferably via remote actuation upon reaching the target site.

25 Figs. 48A-48C show an exemplary application of the embodiment illustrated in Figs. 47A-47C wherein the device 394 is used to close a ventricular septal defect VSD in the septum S between the right and left ventricles RV, LV. Fig. 48 shows the device 394 introduced percutaneously into the right ventricle RV and the component 398 located and expanded in the left ventricle LV. The component 398 is forced against the septum S and the
30 other component 400 is expanded as shown in Fig. 48B. Once expanded, component 400 is forced against the septum S (e.g., by using the sheath 396), attracts the component 398 to close the defect, and the device 394 is removed (Fig 48C).

The preferred embodiments of the invention are described above in detail for

the purpose of setting forth a complete disclosure and for sake of explanation and clarity. It will be readily understood that the scope of the invention defined by the appended claims will encompass numerous changes and modifications.

WHAT IS CLAIMED IS:

- 1 1. A device for forming a magnetic port in a hollow body having a lumen,
2 the device comprising:
3 a component capable of producing a magnetic field and having an opening
4 configured to be placed in communication with the lumen of the hollow body; and
5 a housing disposed on an exterior of the component, the housing providing a
6 substantially sealed enclosure containing the component;
7 wherein the housing is formed of a biocompatible material adapted to be
8 implanted in a patient.
- 1 2. The device of claim 1, wherein the housing provides a hermetically-
2 sealed enclosure containing the component.
- 1 3. The device of claim 1, wherein the housing comprises a plurality of
2 members cooperating to provide the sealed enclosure containing the component.
- 1 4. The device of claim 3, wherein one housing member is a dish and
2 another housing member is configured to close the dish and seal the component therein.
- 1 5. The device of claim 1, wherein the housing comprises a metallic
2 material.
- 1 6. The device of claim 5, wherein the housing comprises a plurality of
2 titanium members joined by welding.
- 1 7. The device of claim 1, wherein the housing includes an indicator of the
2 polarity of the magnetic field produced by the component.
- 1 8. A device adapted to be coupled to tissue using magnetic force, the
2 device comprising:
3 a first securing component capable of producing a magnetic field, the first
4 securing component being adapted to attract a second securing component that is capable of
5 producing a magnetic field; and

6 a magnetic force-increasing mechanism for increasing the magnetic force
7 attracting the first and second securing components when the first securing component is
8 positioned in proximity to the second securing component.

1 9. The device of claim 8, wherein the magnetic force-increasing
2 mechanism has a magnetic permeability greater than 1.0.

1 10. The device of claim 9, wherein the magnetic force-increasing
2 mechanism has a magnetic permeability greater than 100.

1 11. The device of claim 9, wherein the magnetic force-increasing
2 mechanism is configured to alter the magnetic flux density of the first securing component

1 12. The device of claim 11, wherein the magnetic force-increasing
2 mechanism is configured to concentrate magnetic flux in a desired location.

1 13. The device of claim 12, wherein the first securing component is plate-
2 shaped and the flux concentration mechanism comprises a separate channel-shaped strip of
3 material disposed along and forming an extension of at least one edge of the first securing
4 component.

1 14. The device of claim 8, wherein when the first securing component is
2 positioned a given distance from the second securing component the magnetic force attracting
3 the components is from about 5 % to about 75 % higher than the magnetic force attracting the
4 components without the flux concentration mechanism.

1 15. The device of claim 14, wherein when the first securing component is
2 positioned a given distance from the second securing component the magnetic force attracting
3 the components is at least 20 % higher than the magnetic force attracting the components
4 without the flux concentration mechanism.

1 16. The device of claim 14, further comprising a second securing
2 component sized and configured generally complementarily to the first securing component,
3 wherein the second securing component is capable of producing a magnetic field that attracts
4 the first securing component and includes a flux concentration mechanism.

1 17. The device of claim 16, wherein the first securing component includes
2 a portion for mechanically engaging the second securing component device to couple the
3 securing components mechanically and by magnetic force.

1 18. A device adapted to be coupled to a blood vessel having a lumen so as
2 to produce a magnetic field adjacent the blood vessel, the device comprising:

3 at least one securing component sized and configured to be secured to a blood
4 vessel having a lumen, the one securing component being capable of producing a magnetic
5 field;

6 wherein the one securing component has an indicator that indicates the polarity
7 of the magnetic field to a user carrying out a procedure on the blood vessel.

1 19. The device of claim 18, wherein the indicator comprises a visual
2 marker on the one securing component that indicates a selected polarity of the magnetic field.

1 20. The device of claim 18, further comprising a delivery device
2 supporting the one securing component, and wherein the indicator comprises a predetermined
3 portion of the one securing component that is aligned with the delivery device to ensure that
4 the one securing component is located with the selected polarity oriented in a desired
5 position.

1 21. The device of claim 18, further comprising a second securing
2 component that produces a magnetic field and is attracted to the one securing component,
3 wherein the second component also has an indicator that indicates the polarity of the magnetic
4 field produced by the second component to ensure that the securing components are
5 positioned to ensure their attraction.

1 22. The device of claim 21, wherein the one securing component is
2 adapted to be coupled to a target vessel to form a magnetic port that communicates with the
3 vessel lumen, and the second securing component is adapted to be coupled to the one
4 securing component to form a vascular anastomosis using magnetic force.

1 23. The device of claim 18, wherein the one securing component
2 comprises an electromagnet coupled to a power source.

1 24. The device of 23, wherein the electromagnet is contained in a
2 protective housing.

1 25. A device for forming a port in a first hollow body having a lumen, the
2 device comprising:

3 a securing component having an opening adapted to be placed in
4 communication with an opening in the wall of the first hollow body so as to be in
5 communication with the lumen of the first hollow body; and

6 a mechanical attachment portion configured to secure the component to the
7 first hollow body in a desired position;

8 wherein the securing component is configured to produce a magnetic field
9 adjacent the opening in the first hollow body.

1 26. The device of claim 25, wherein the mechanical attachment portion
2 comprises a structure that is at least partially collapsible for delivery through the opening in
3 the wall of the first hollow body and then expandable to engage the wall of the first hollow
4 body.

1 27. The device of claim 26, wherein the collapsible structure comprises a
2 tube with self-expanding arms that are generally coplanar for contacting the wall of the first
3 hollow body when the arms are expanded.

1 28. The device of claim 27, wherein the tube defines an opening that is
2 aligned with the opening in the securing component.

1 29. The device of claim 25, wherein the securing component has a
2 laminated structure and includes a layer of biocompatible material to enhance sealing of the
3 opening in the wall of the first hollow body.

1 30. The device of claim 29, wherein the attachment portion is secured to a
2 separate member formed of a material capable of producing a magnetic field.

1 31. The device of claim 25, wherein the mechanical attachment portion is
2 adapted to provide the sole attachment between the securing component and the first hollow
3 body.

1 32. The device of claim 25, wherein the opening in the securing
2 component has a shape selected from the group consisting of circular, elliptical, racetrack,
3 football and canoe-shaped configurations.

1 33. A delivery device in combination with a component for forming an
2 anastomosis, the combination comprising:

3 at least one component having an opening adapted to be placed in
4 communication with a lumen of a vessel in a patient's body, the component being capable of
5 producing a magnetic field; and

6 a delivery device including a support portion supporting the component and a
7 retaining portion that is movable with respect to the support portion, wherein the retaining
8 portion is placed in a first position to retain the component and is moved from the first
9 position to release the component;

10 wherein the retaining portion is movable with respect to the support portion in
11 a direction selected from the group consisting of axial and rotary directions.

1 34. The combination of claim 33, further comprising a portion for
2 supporting a second component, and wherein the support portion and the retaining portion of
3 the delivery device are configured to contact different areas of the component.

1 35. The combination of claim 33, wherein the retaining portion comprises
2 a rotatable rod with a portion contacting the component.

1 36. The combination of claim 33, wherein the retaining portion comprises
2 a wedge slidably disposed with respect to the support portion, the wedge contacting the
3 component when the retaining portion is in the first position.

1 37. The combination of claim 33, wherein the delivery device has a
2 delivery end adapted to support at least one component, and the delivery end is laterally offset
3 with respect to a longitudinal axis of the delivery device.

1 38. The combination of claim 37, wherein the delivery end has a notch
2 adapted to receive tissue as the device is being used to introduce the component into the
3 lumen of a vessel.

1 39. The combination of claim 33, wherein the component comprises a
2 magnetic material and the delivery device comprises a ferromagnetic material.

1 40. A method for increasing the magnetic force between first and second
2 anastomotic securing components, the method comprising steps of:

3 (a) providing first and second anastomotic securing components each of
4 which is capable of producing a magnetic field, the first and second securing components
5 having respective openings adapted to be placed in communication with each other; and

6 (b) increasing the magnetic force between the first and second securing
7 components by concentrating magnetic flux between the securing components.

1 41. The method of claim 40, wherein step (b) is performed by altering the
2 construction of at least one of the first and second securing components to concentrate
3 magnetic flux between the components.

1 42. The method of claim 40, wherein step (b) is performed by providing
2 the first and second securing components with respective flux concentration mechanisms that
3 are formed of a material having a higher magnetic permeability than air.

1 43. A method for coupling a securing component to a target vessel in order
2 to form a magnetic port communicating with a lumen of the target vessel, the method
3 comprising steps of:

4 (a) providing at least one securing component capable of producing a
5 magnetic field and having an opening adapted to be placed in communication with the lumen
6 of the target vessel;

7 (b) coupling the one securing component to the target vessel with the opening
8 in the one securing component communicating with the target vessel lumen; and

9 (c) prior to completing step (b) confirming the orientation of the polarity of
10 the magnetic field produced by the one securing component.

1 44. The method of claim 43, wherein step (c) is performed by pre-loading
2 the securing component on a delivery device in a predetermined position that properly orients
3 the polarity of the magnetic field.

1 45. The method of claim 44, wherein the delivery device removably
2 supports the one securing component to allow removal and reloading of the component if the
3 polarity is improperly oriented.

1 46. The method of claim 43, wherein step (a) is performed by providing
2 first and second anastomotic securing components each of which is capable of producing a
3 magnetic field, step (b) is performed by positioning the securing components against opposite
4 surfaces of the wall of the target vessel, and step (c) is performed by checking a visual marker
5 carried on at least one of the securing components.

1 47. A method for forming a magnetic port in a first hollow body located
2 within a patient, the first hollow body having a lumen, the method comprising steps of:

3 (a) forming an opening in a wall of the first hollow body, the opening
4 extending into the lumen of the first hollow body;

5 (b) providing a first securing component capable of producing a magnetic
6 field and having an opening adapted to be placed in communication with the opening in the
7 wall of the first hollow body; and

8 (c) coupling the first securing component to the first hollow body by a
9 mechanical attachment to form a magnetic port in the first hollow body.

1 48. The method of claim 47, wherein the first securing component is
2 coupled to the first hollow body solely by a mechanical attachment.

1 49. The method of claim 47, further comprising the steps of providing a
2 second securing component capable of producing or being attracted by a magnetic field,
3 joining the second securing component to a second hollow body, and coupling the second
4 securing component to the magnetic port created according to step (c) to form an end-to-side
5 anastomosis between the first and second hollow bodies.

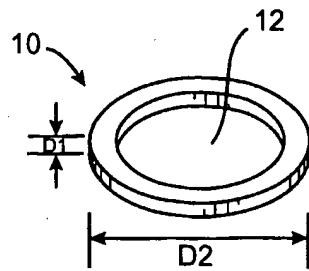


FIG. 1

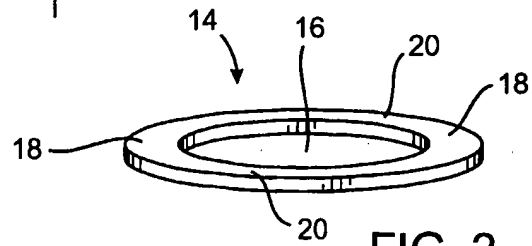


FIG. 2

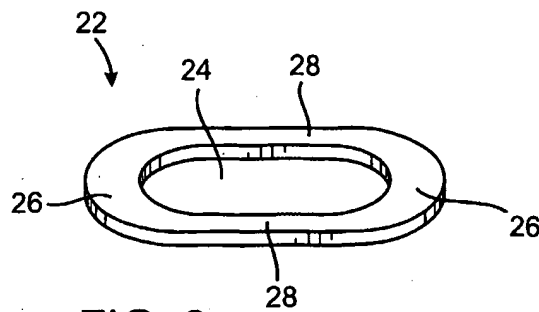


FIG. 3

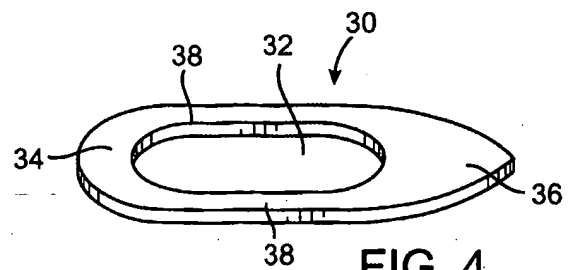


FIG. 4

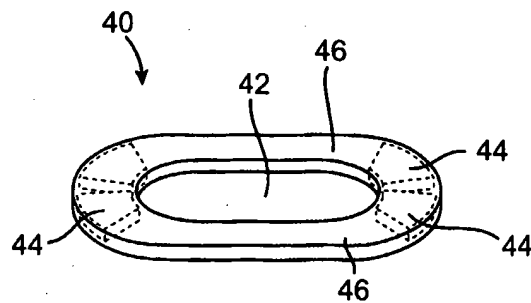


FIG. 5

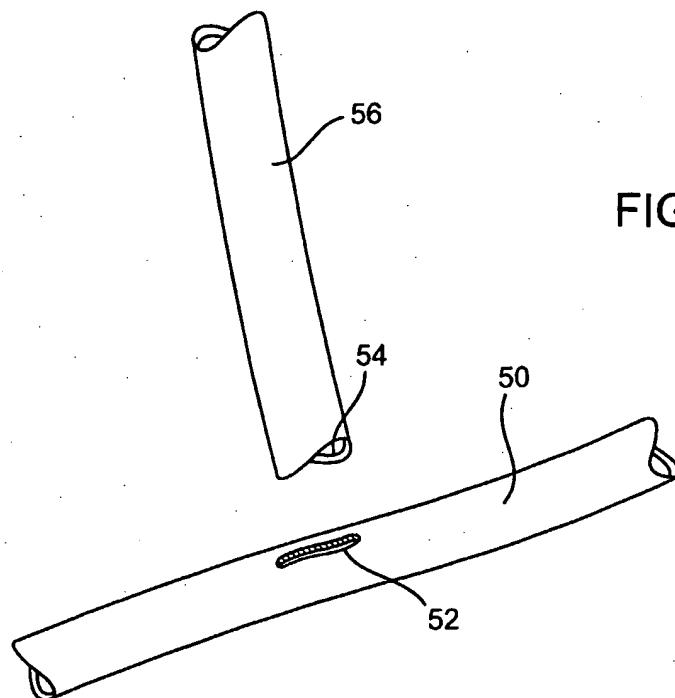


FIG. 6

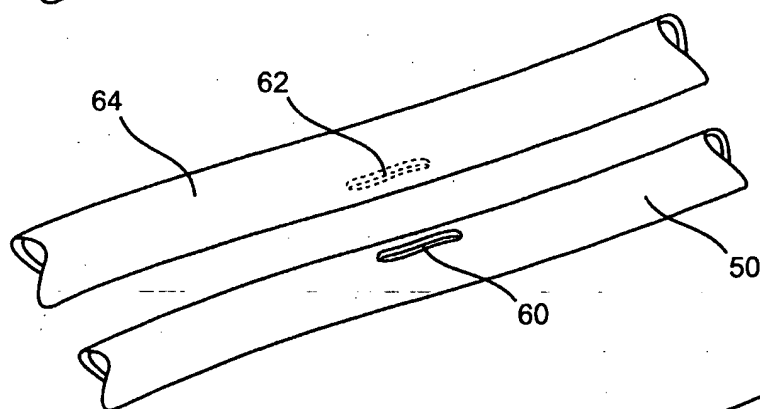


FIG. 7

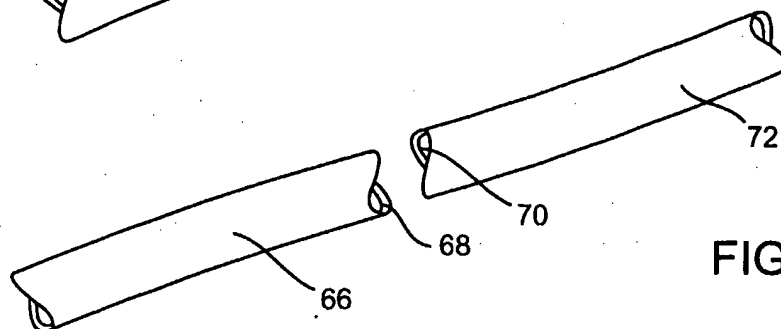
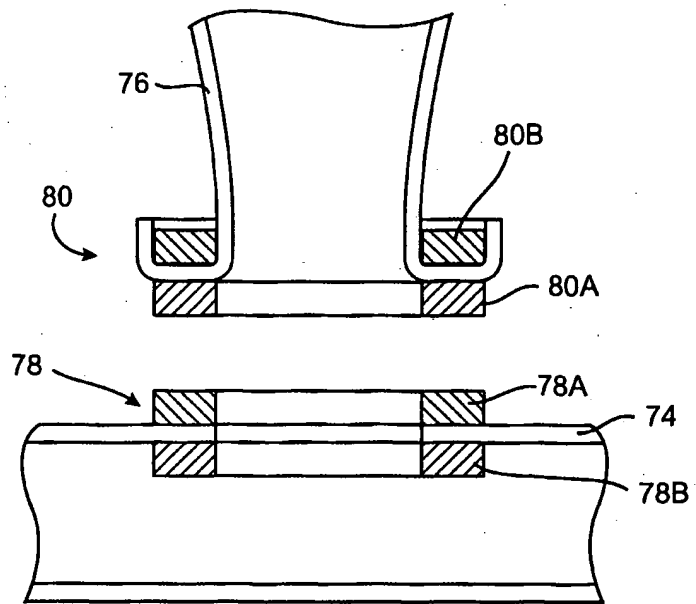
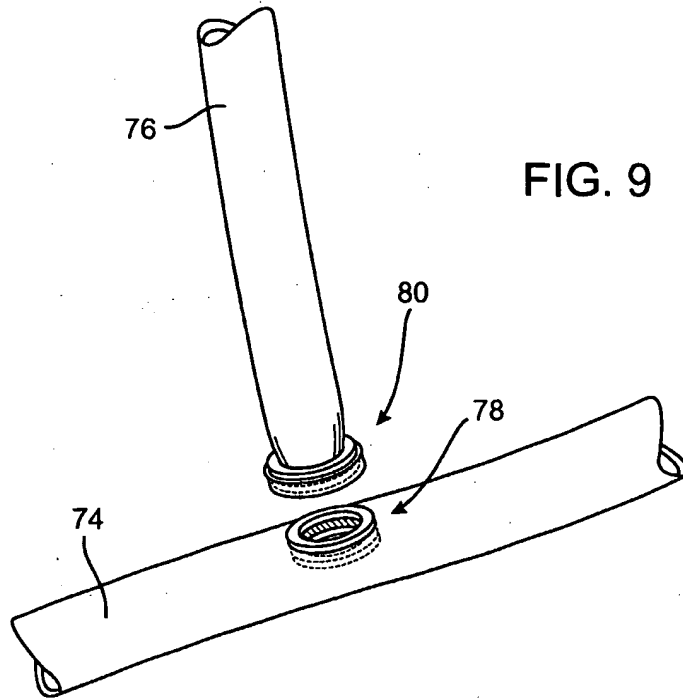


FIG. 8



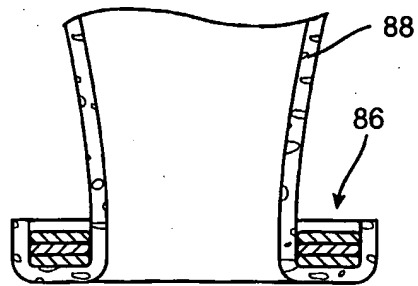


FIG. 10A

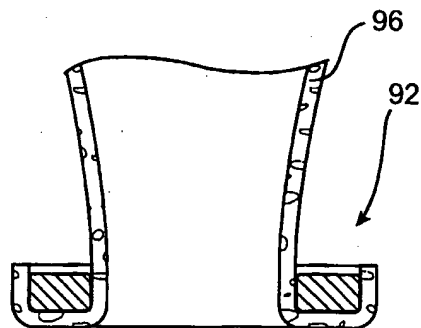
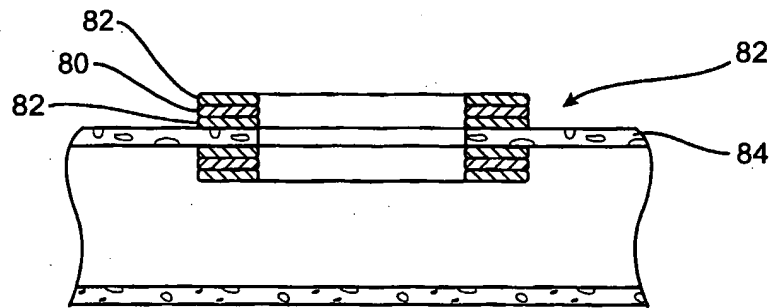
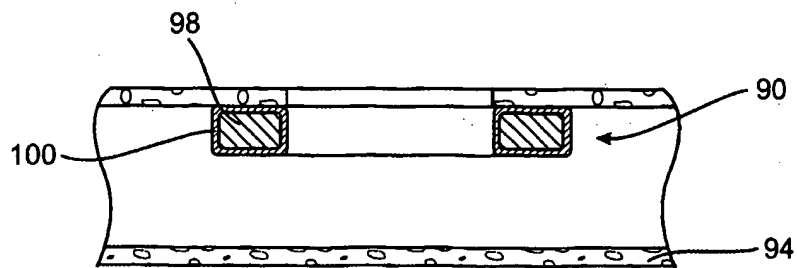
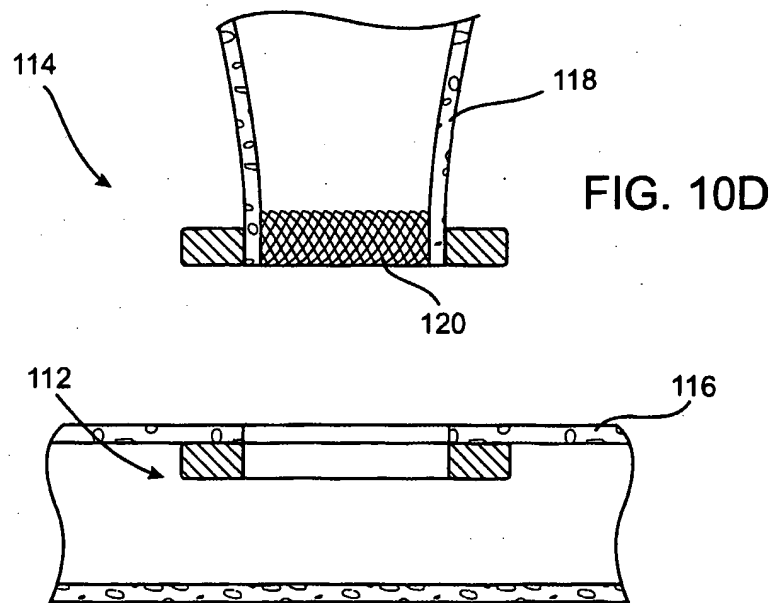
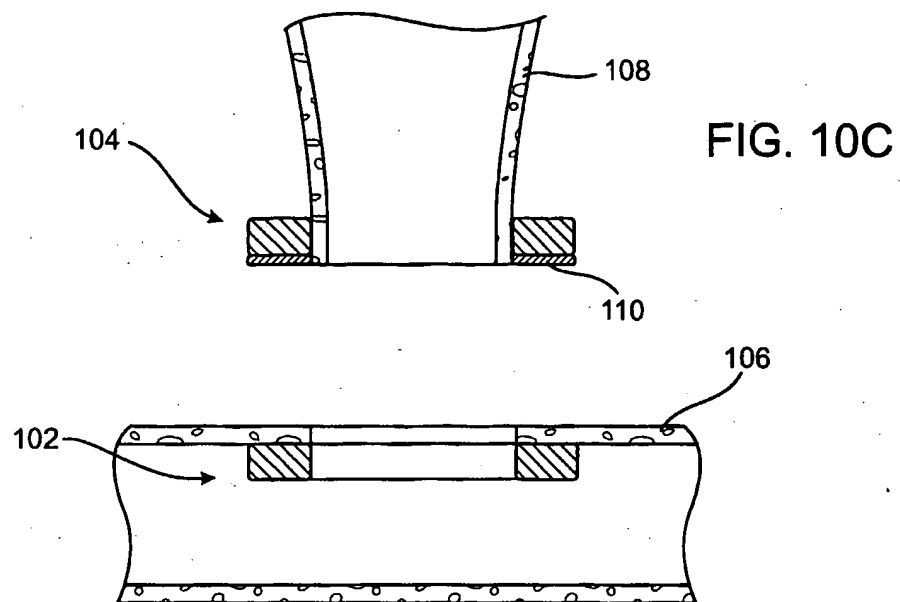
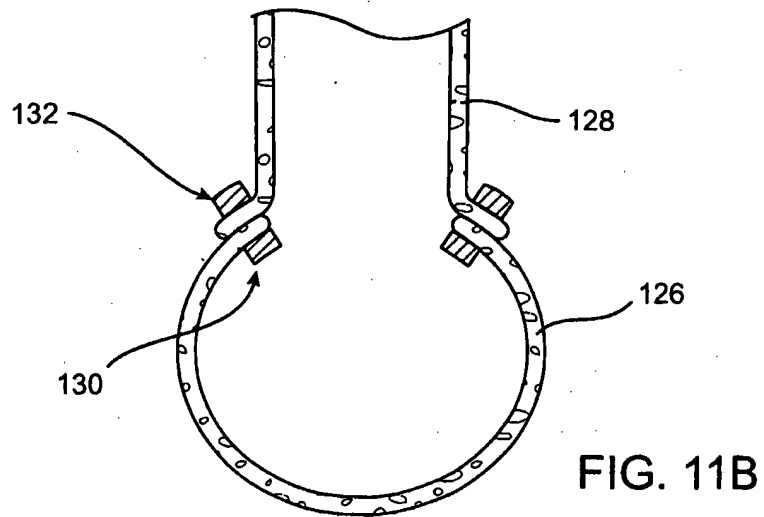
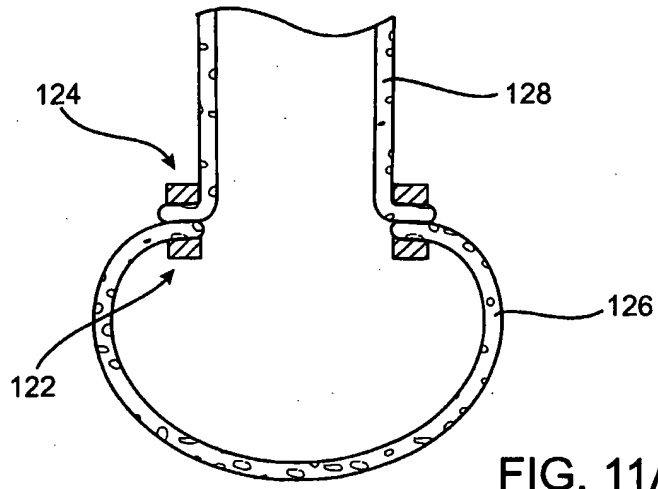
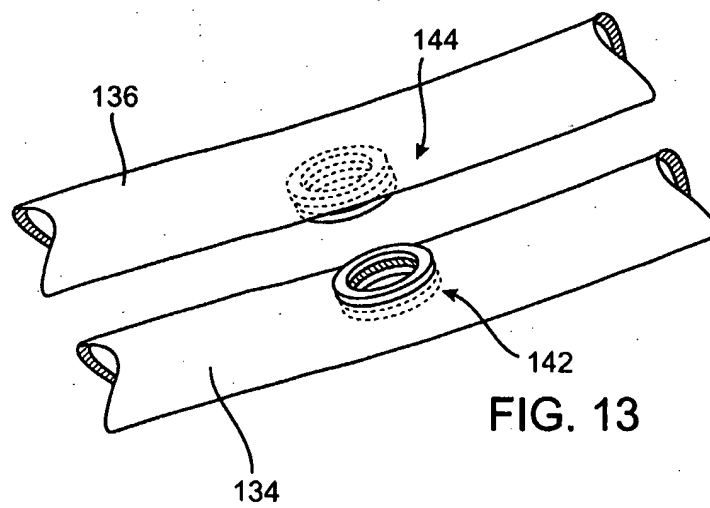
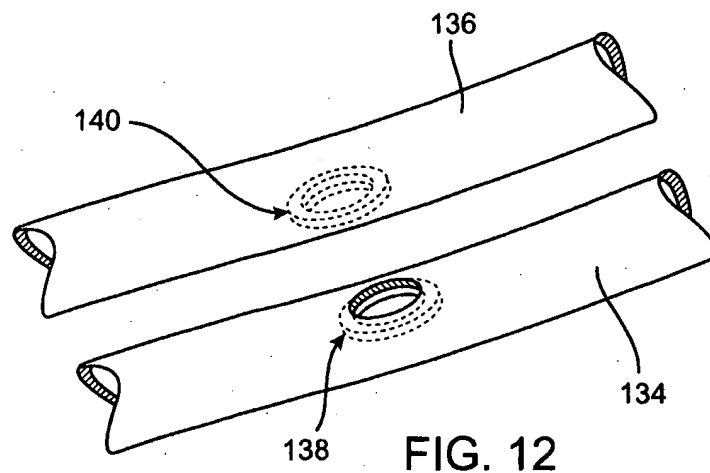


FIG. 10B









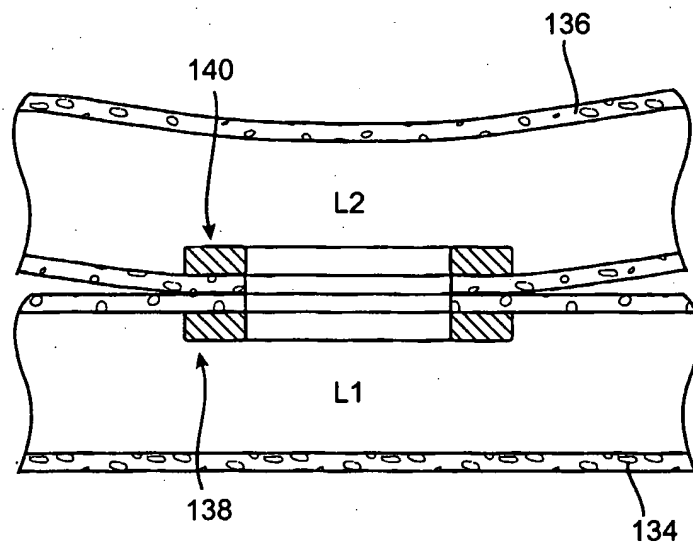


FIG. 14A

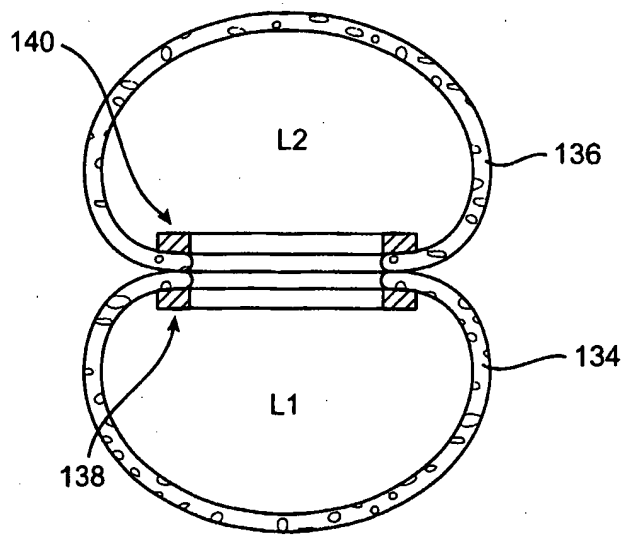


FIG. 14B

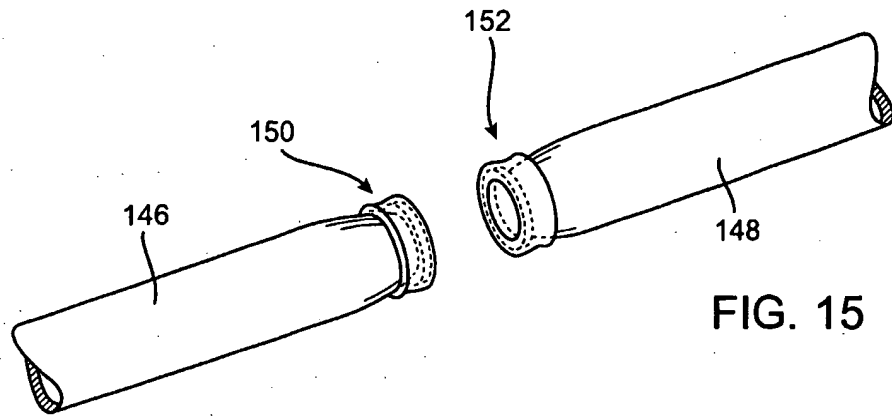


FIG. 15

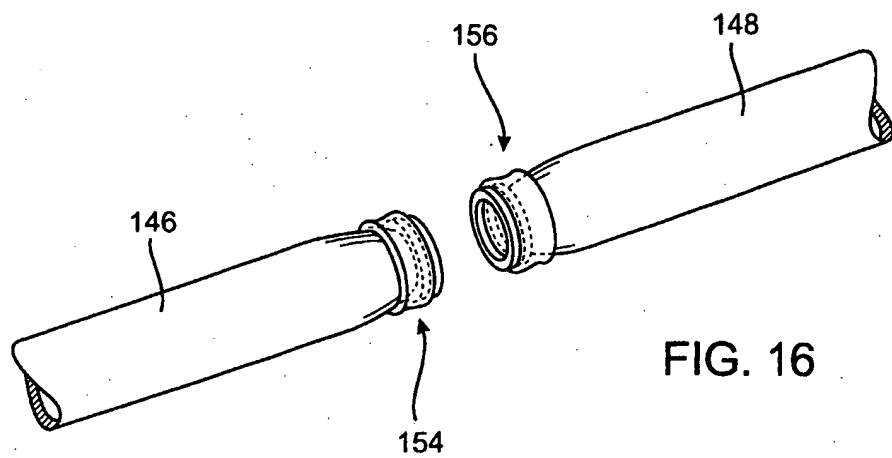


FIG. 16

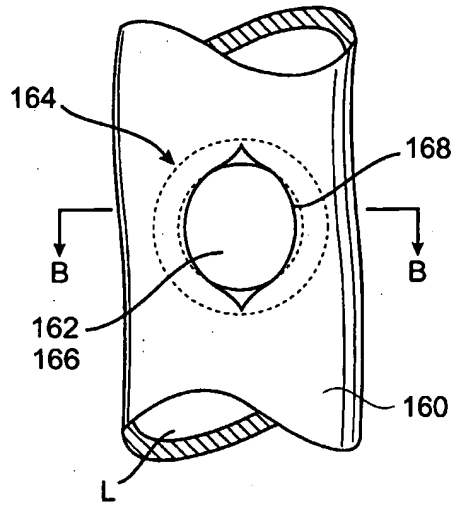


FIG. 17A

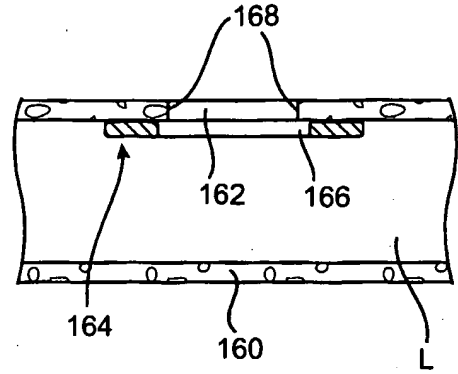


FIG. 17B

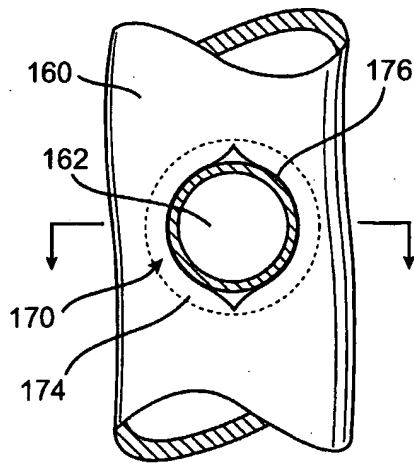


FIG. 18A

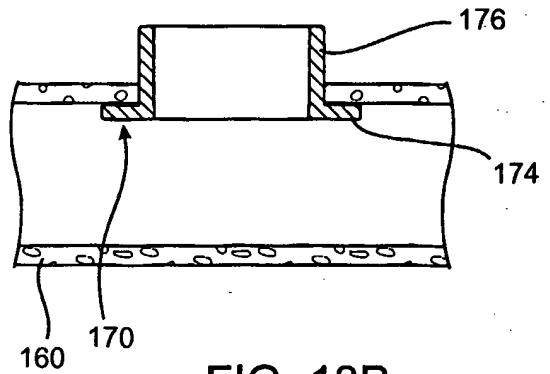
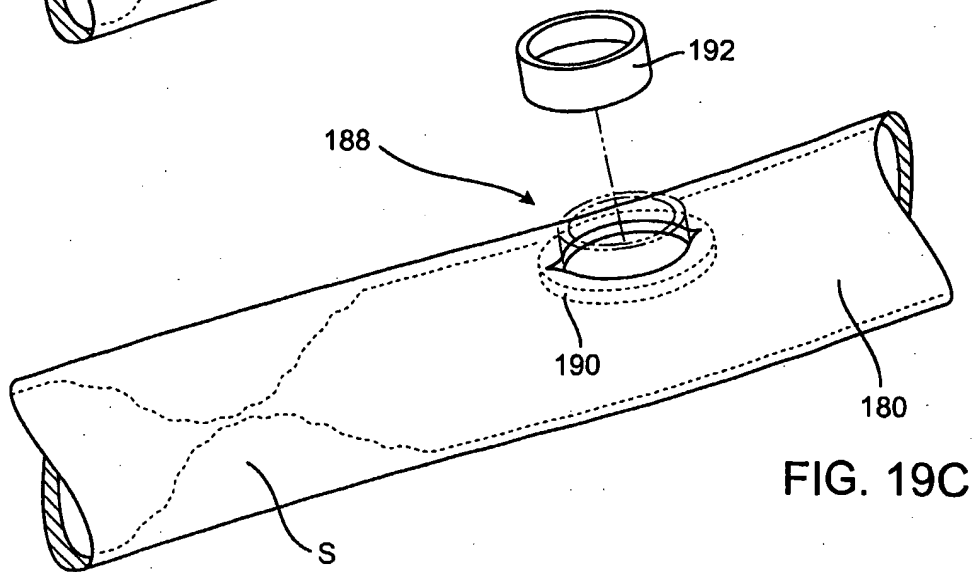
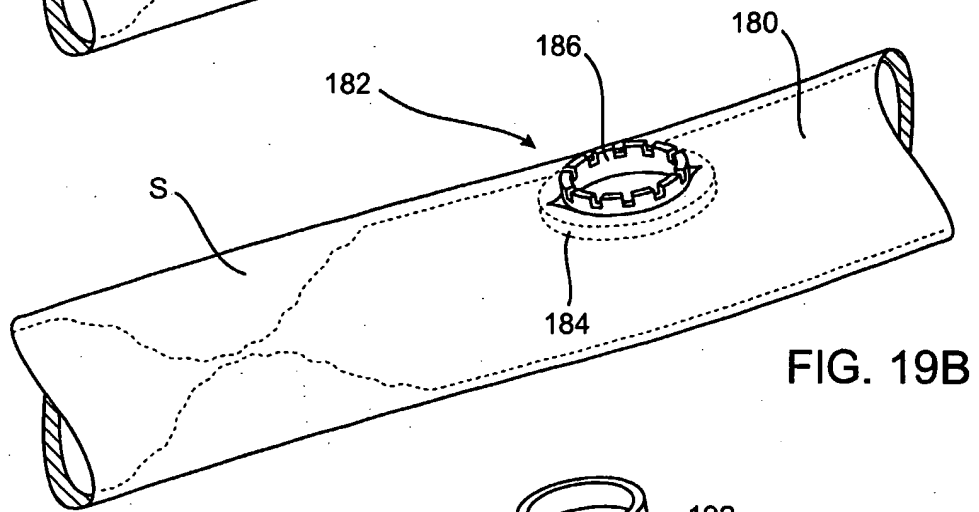
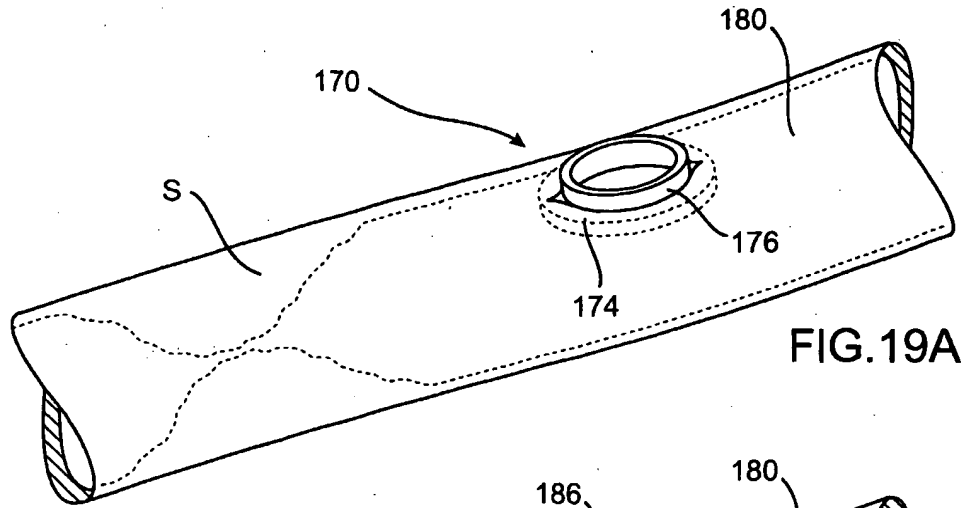
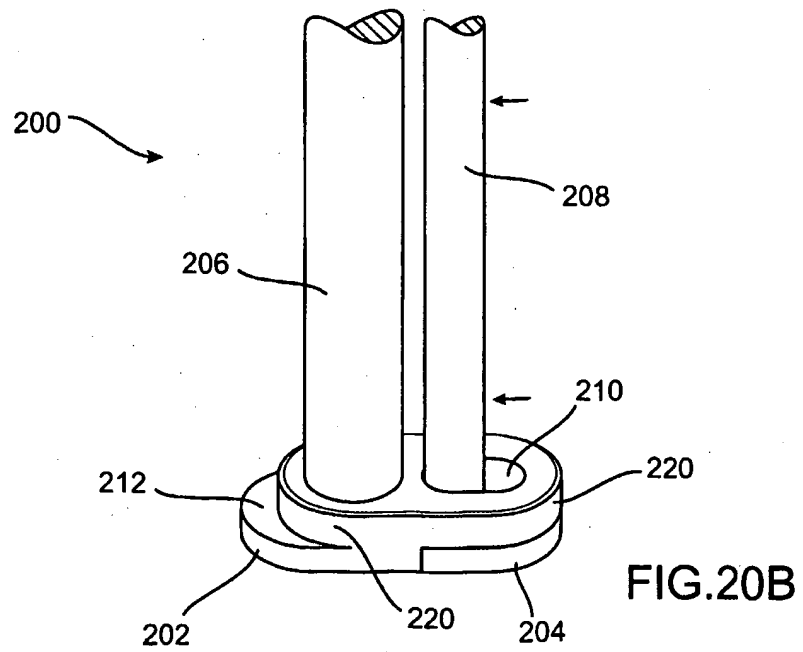
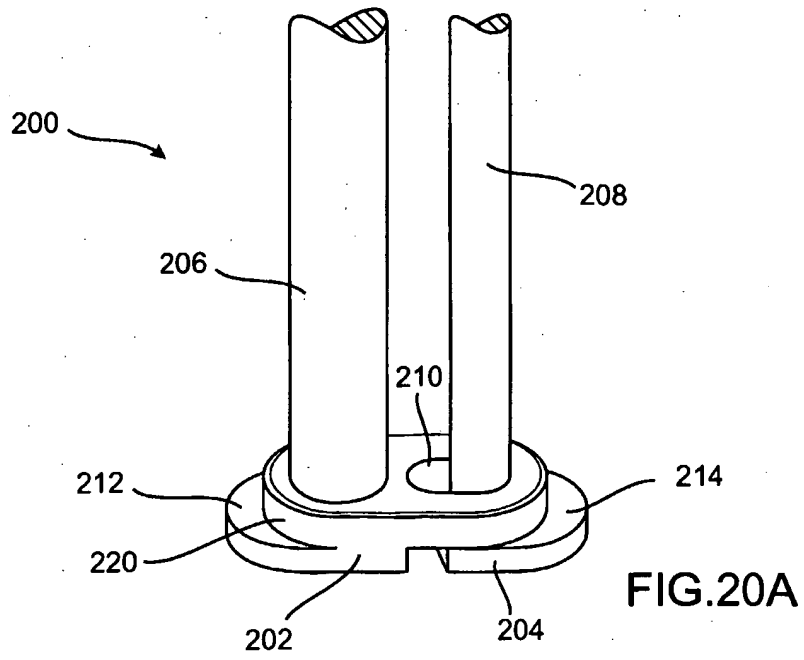


FIG. 18B





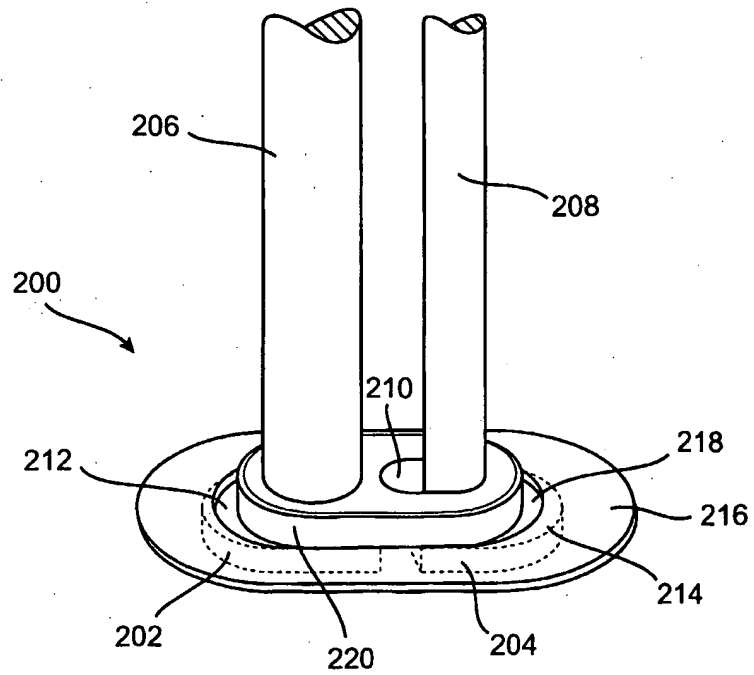


FIG. 21A

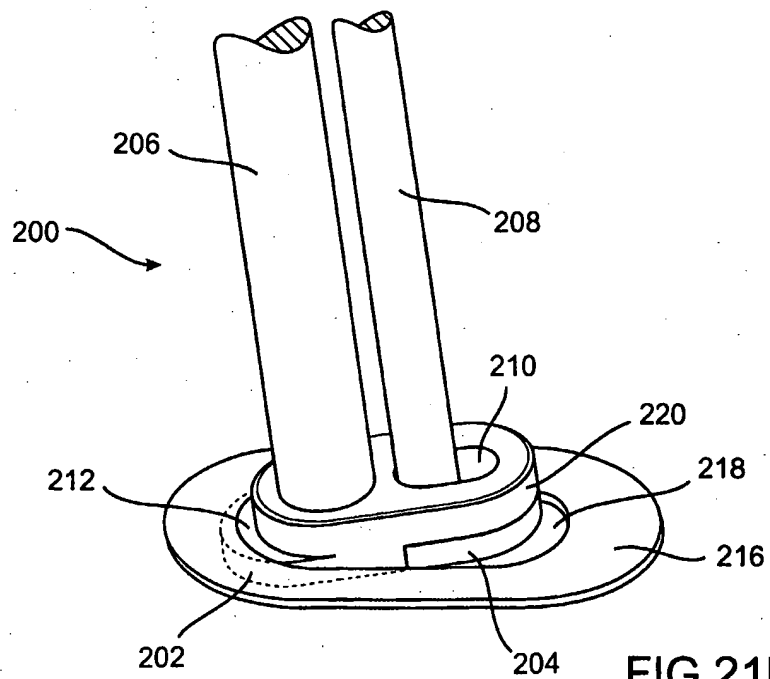


FIG. 21B

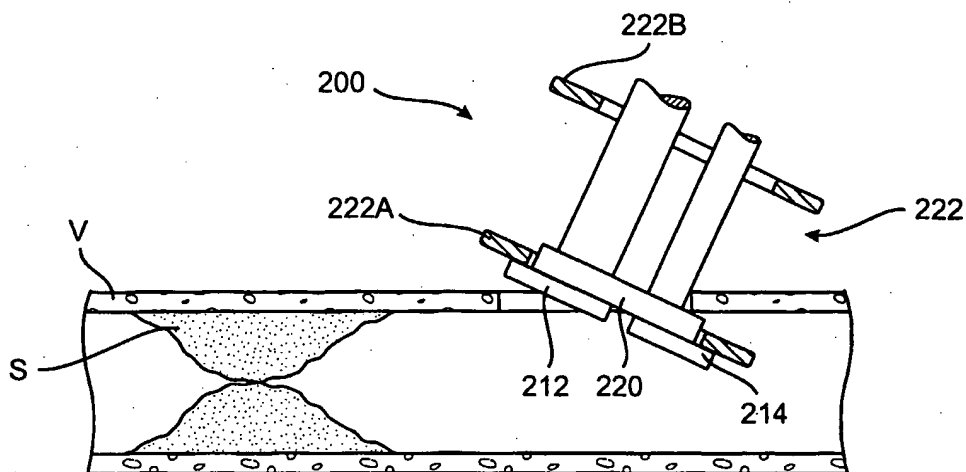


FIG. 22A

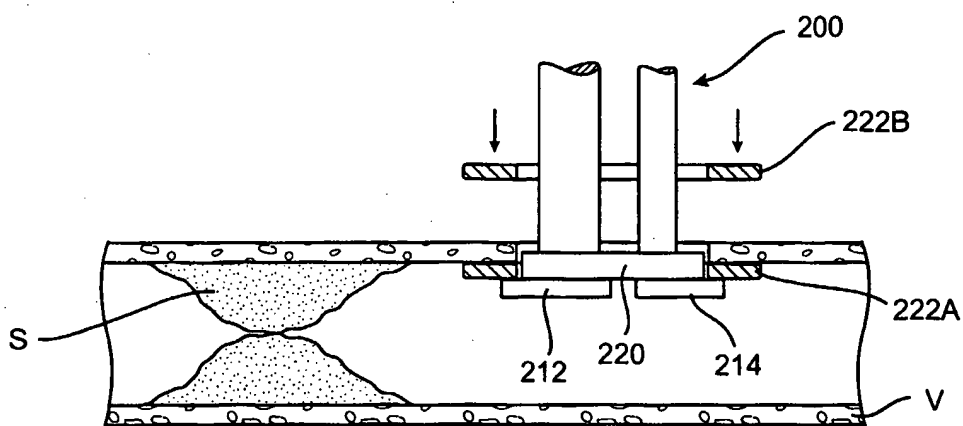


FIG. 22B

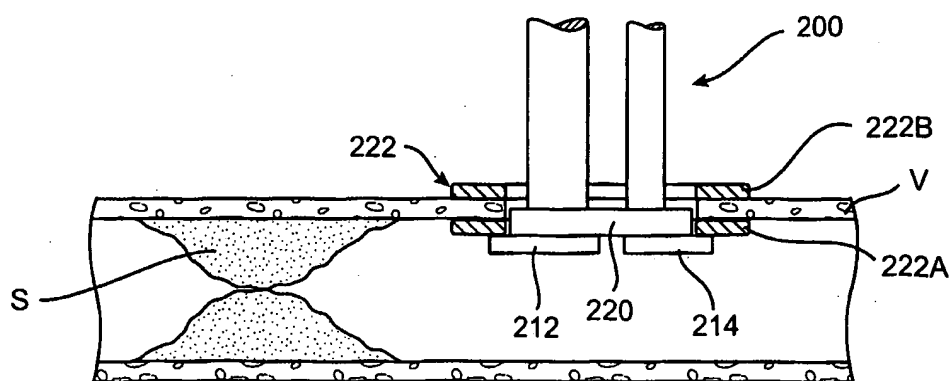
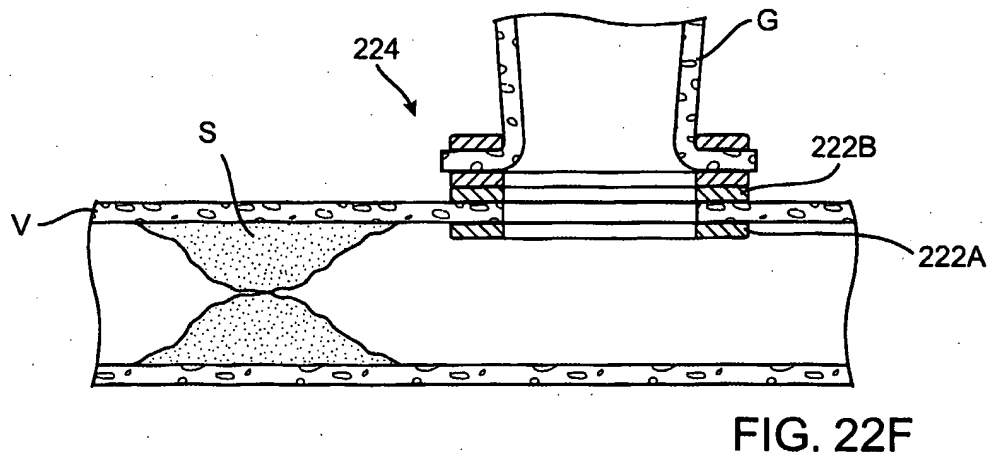
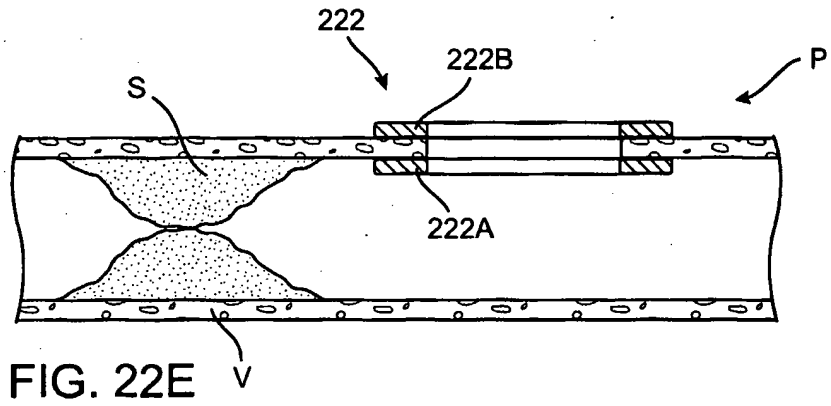
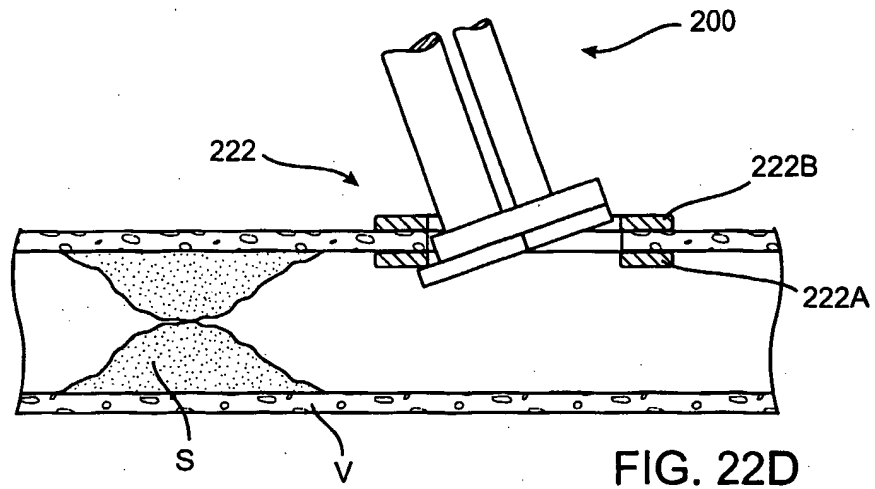
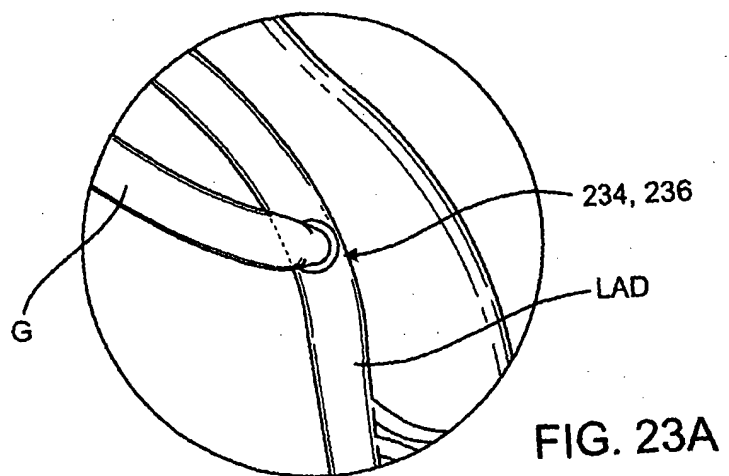
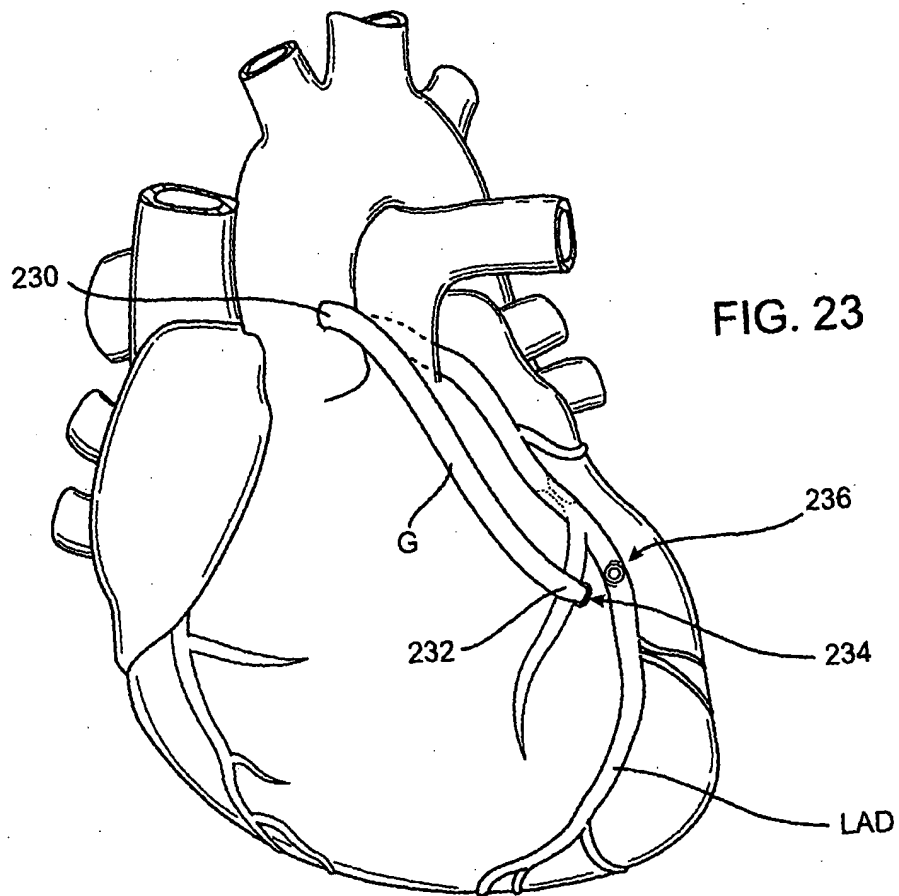
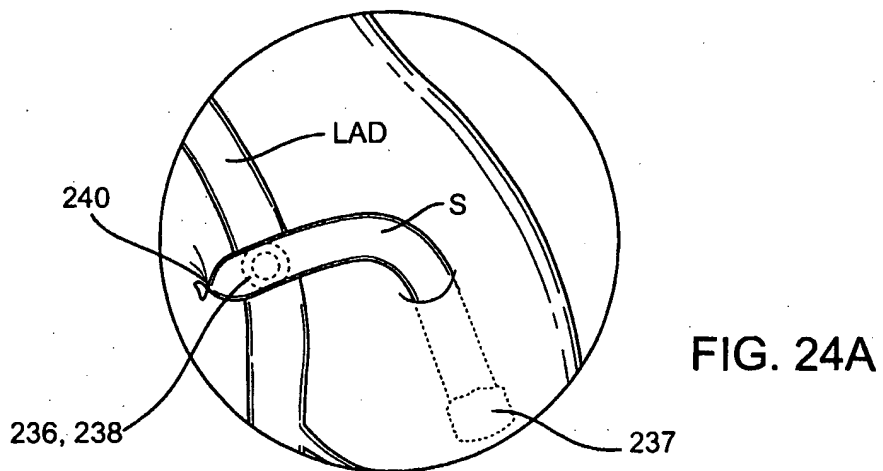
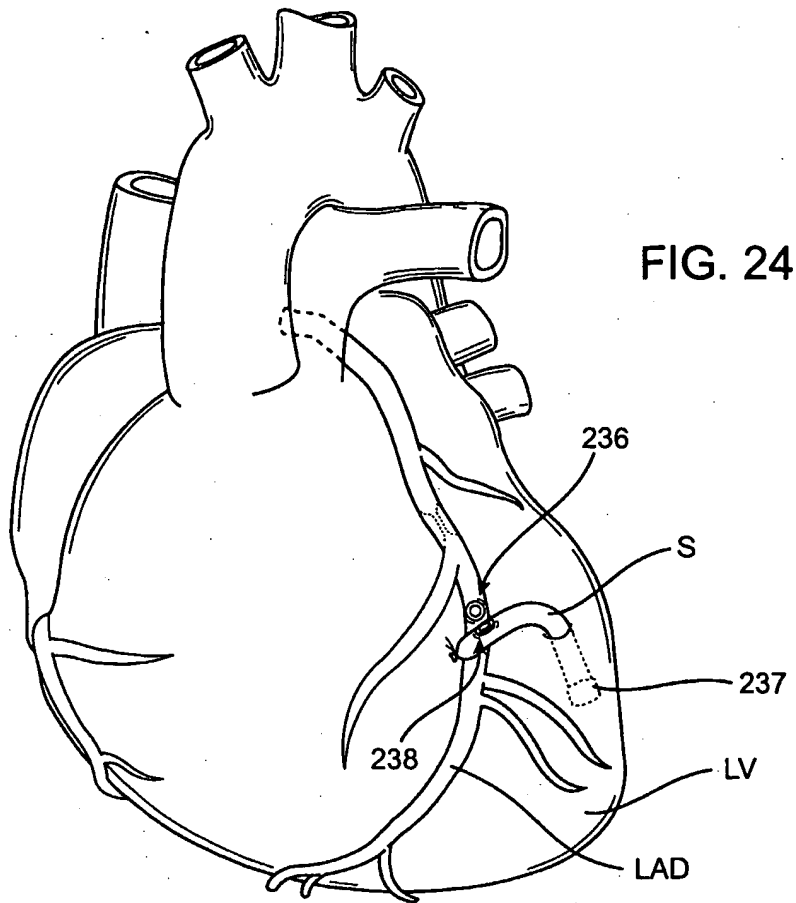


FIG. 22C







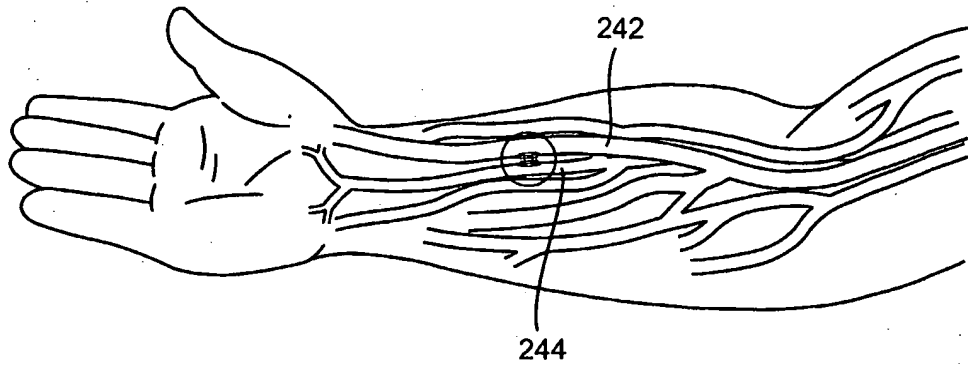


FIG. 25

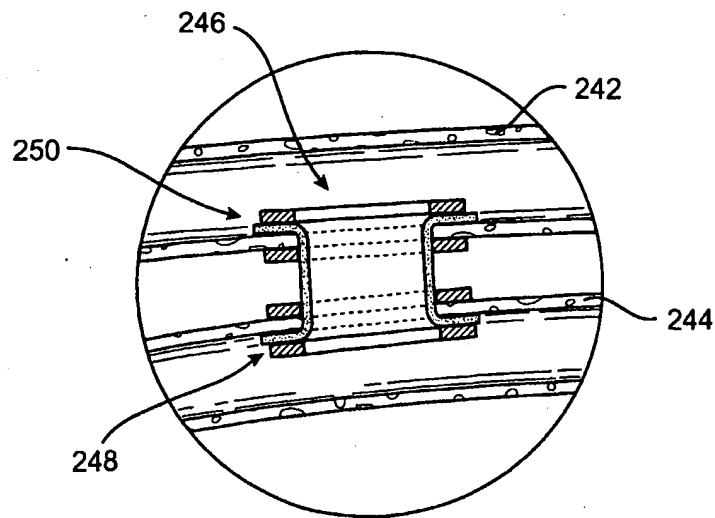


FIG. 25A

FIG. 26A

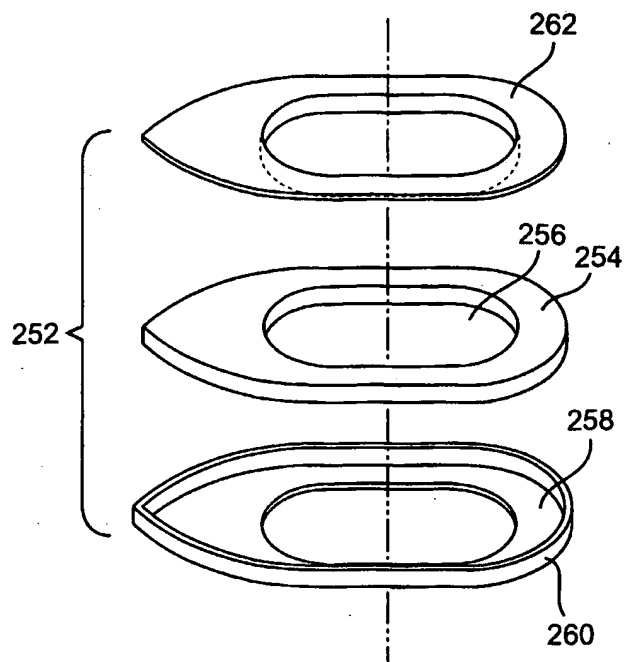


FIG. 26B

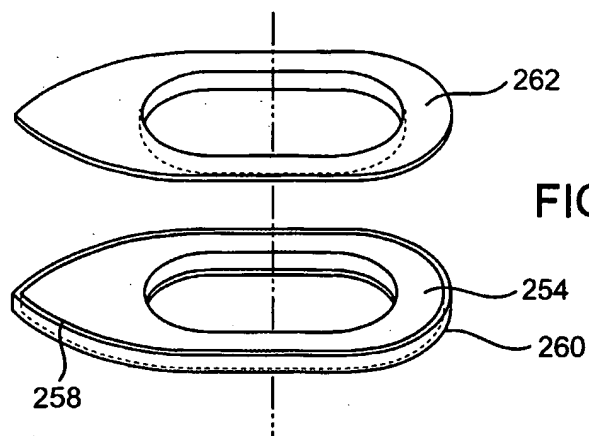
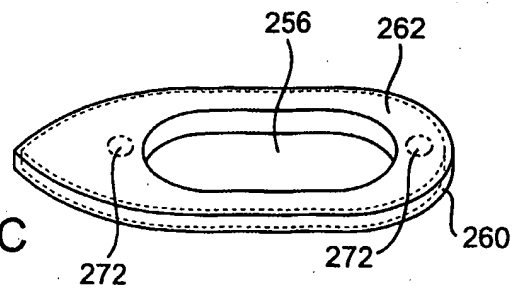


FIG. 26C



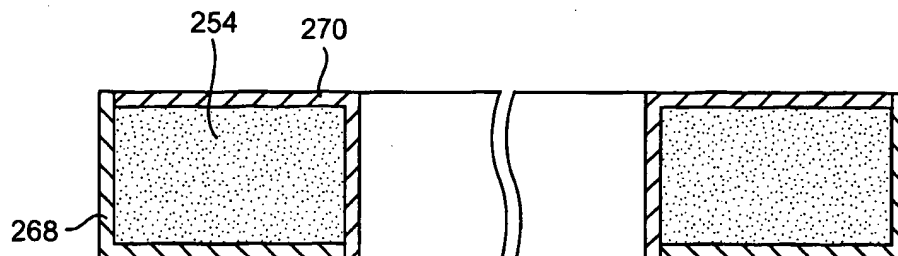


FIG. 27B

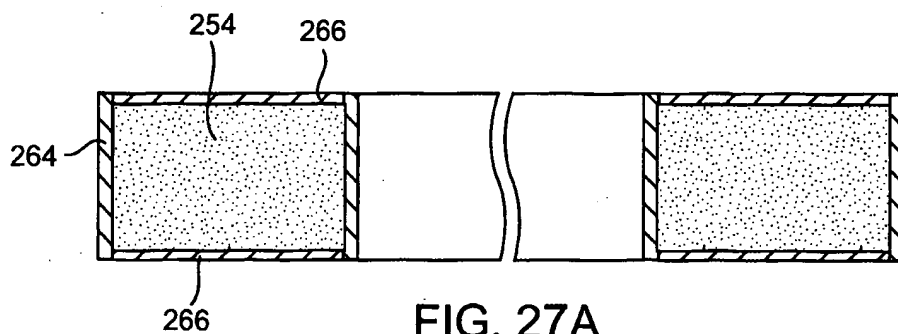


FIG. 27A

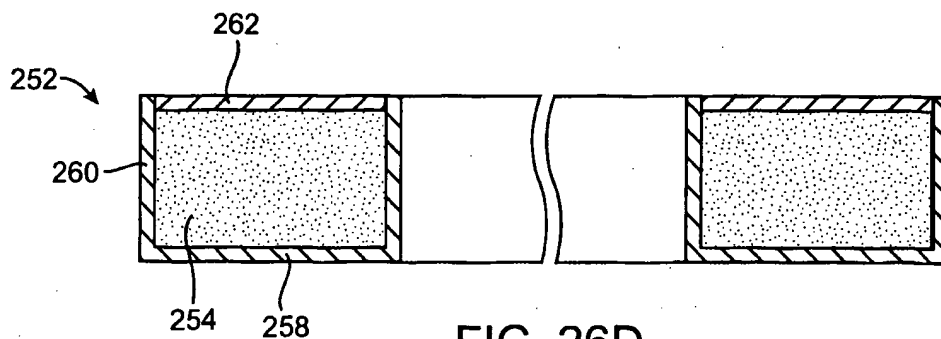


FIG. 26D

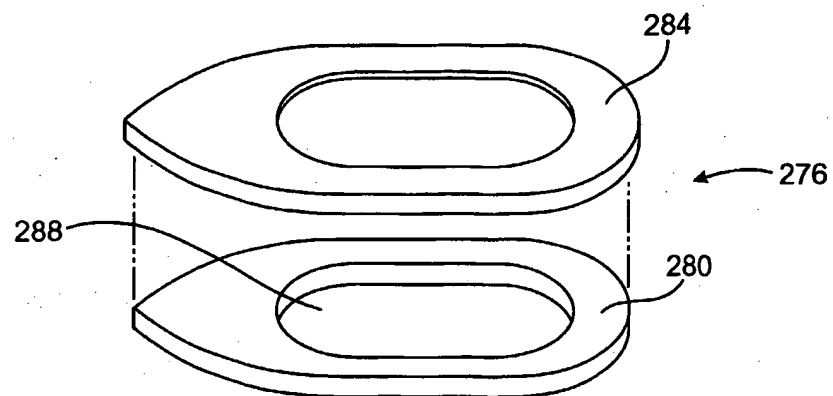


FIG. 28

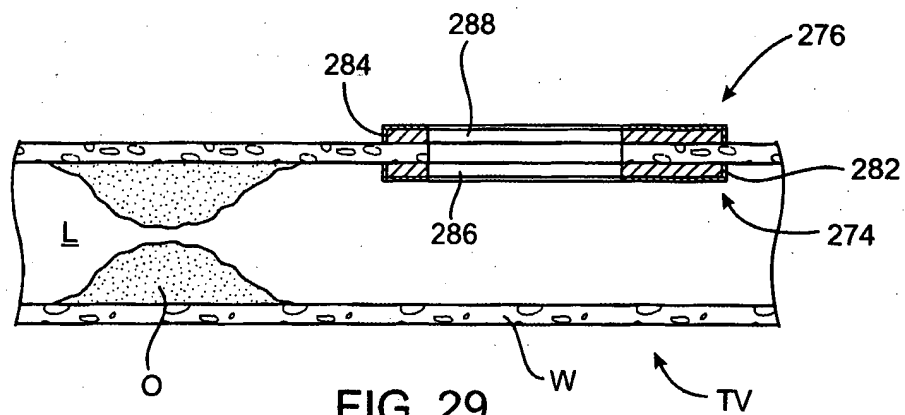
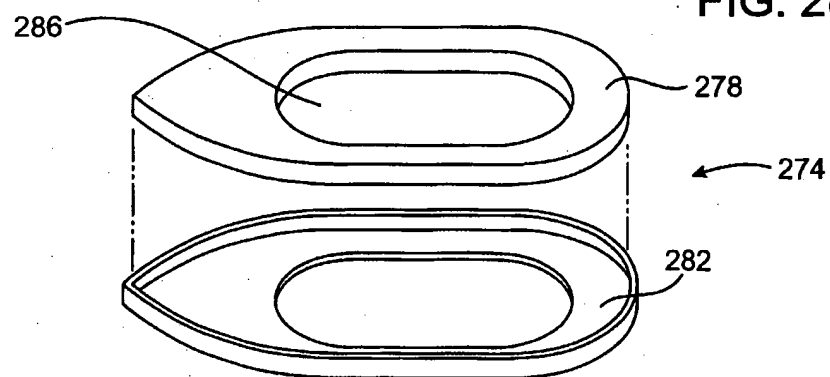


FIG. 29

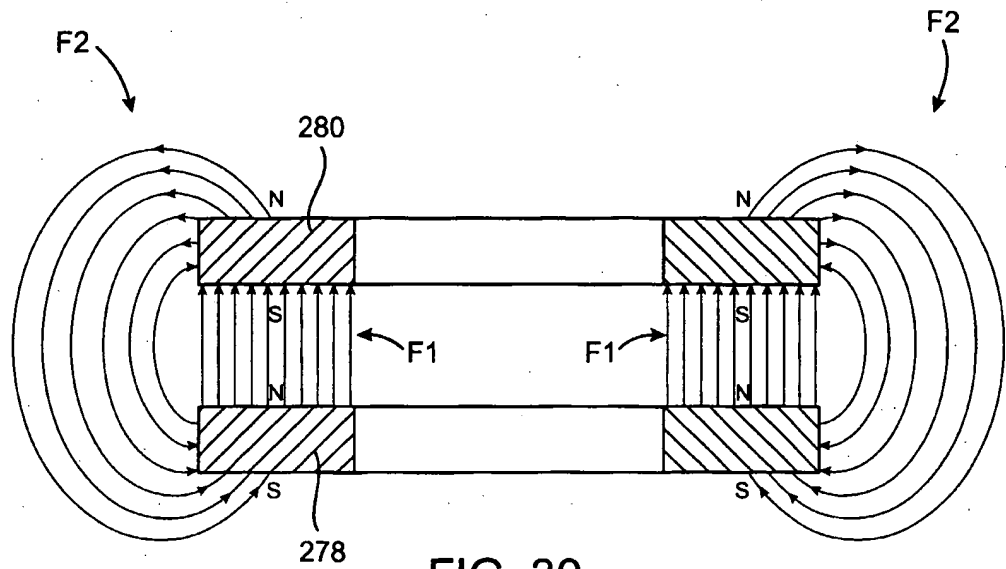


FIG. 30

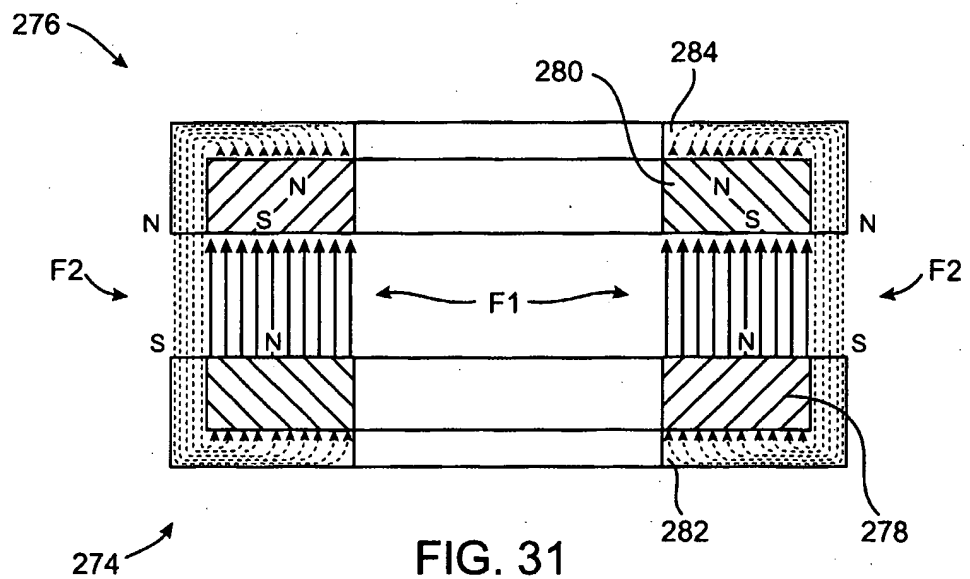


FIG. 31

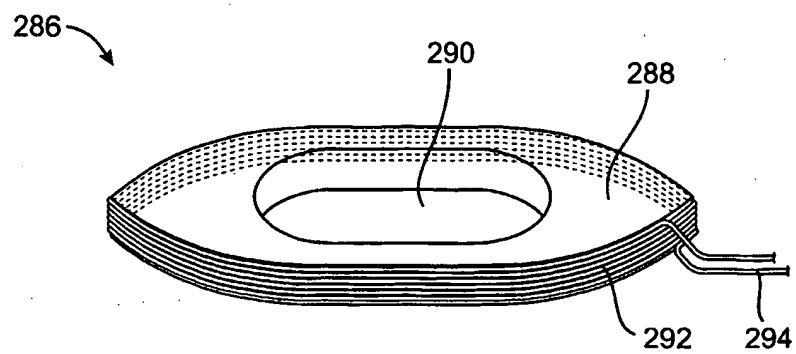


FIG. 32A

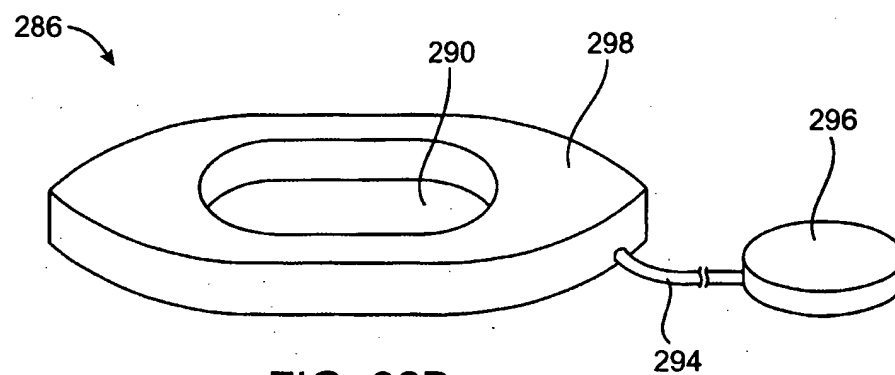


FIG. 32B

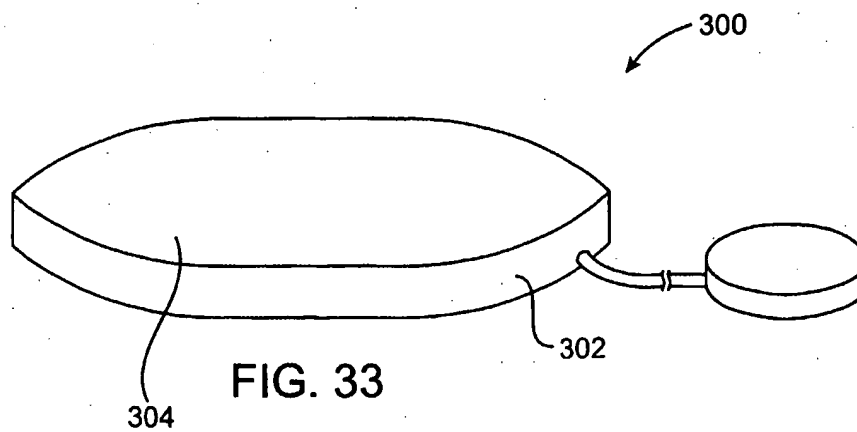
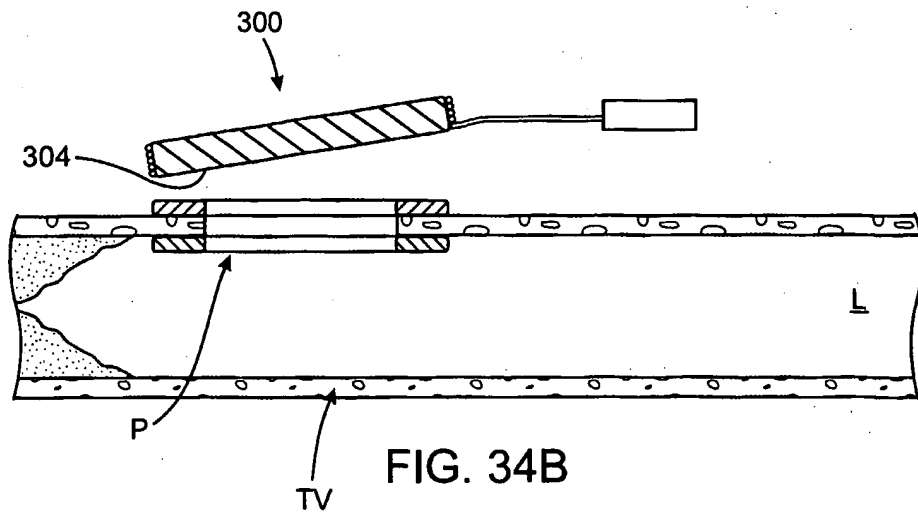
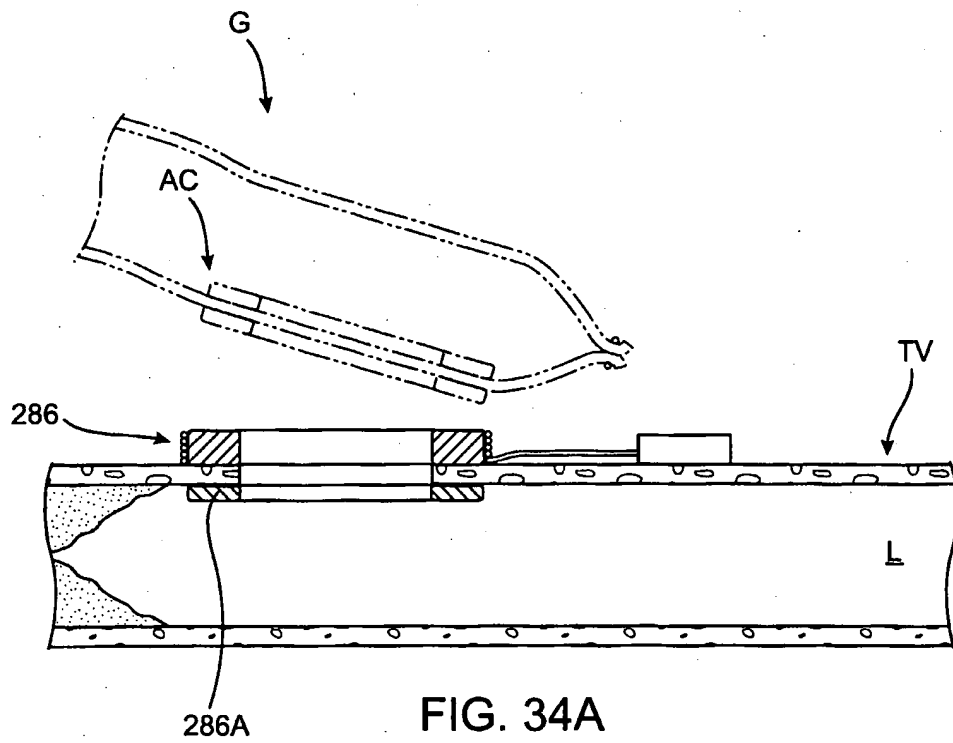
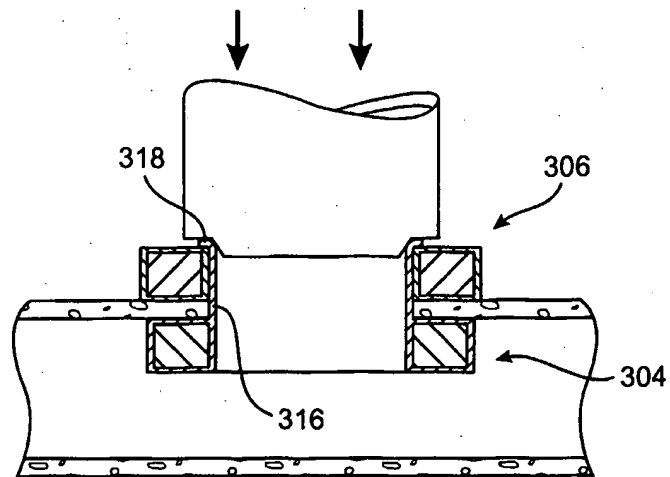
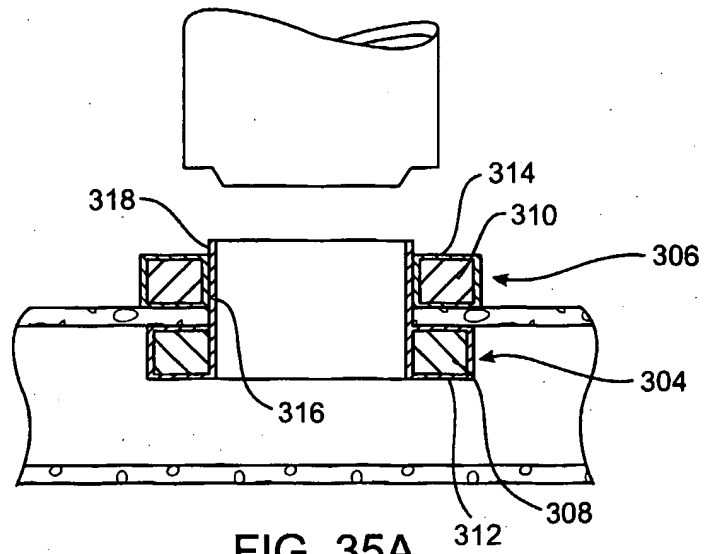
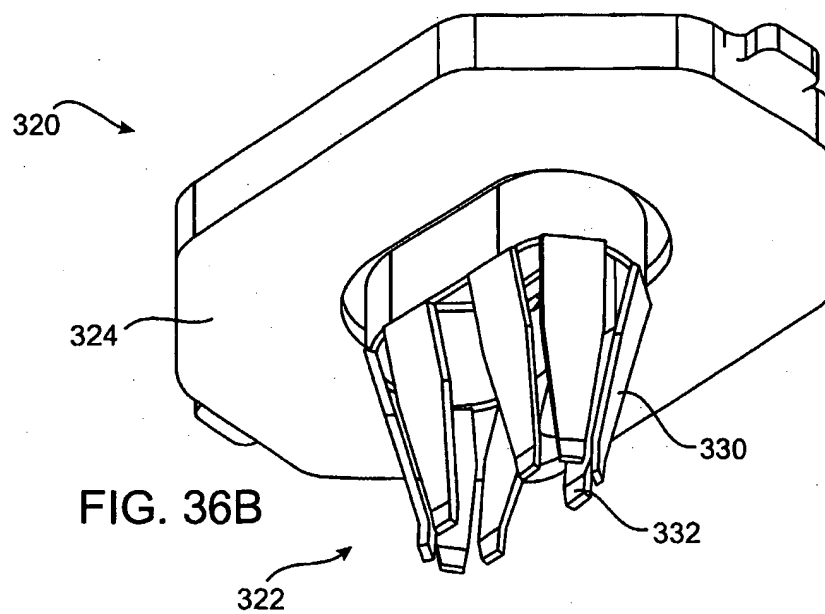
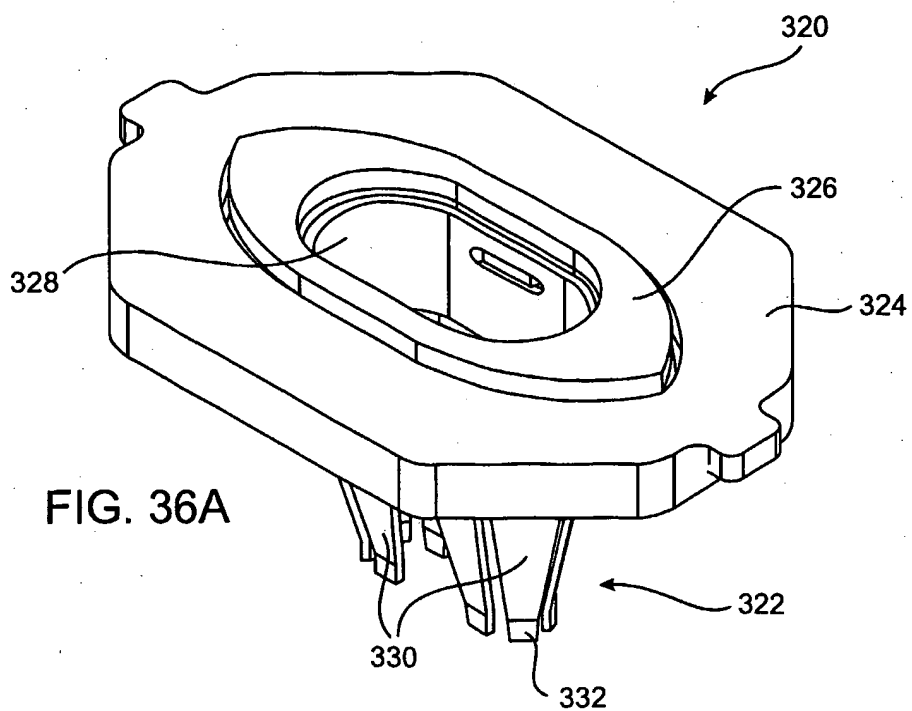
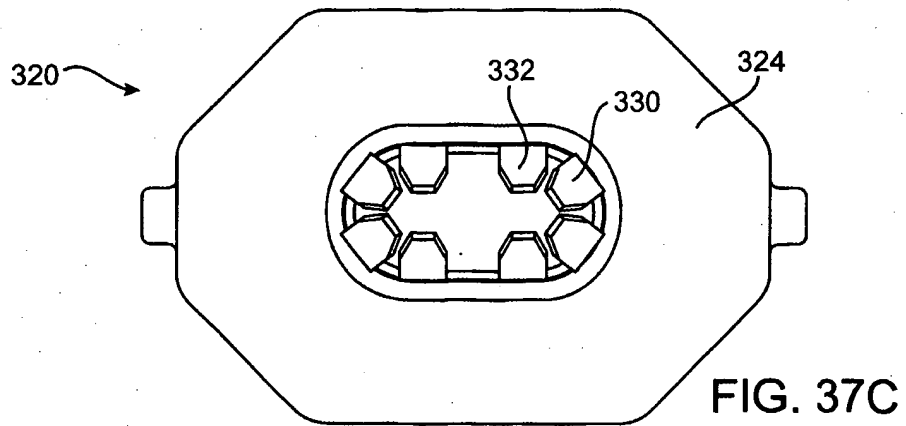
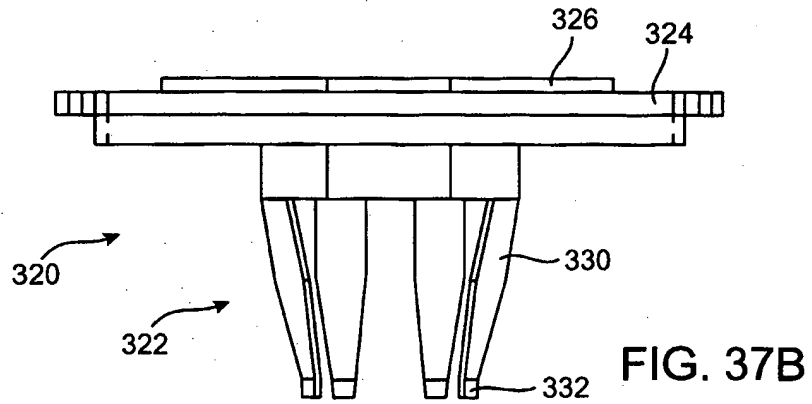
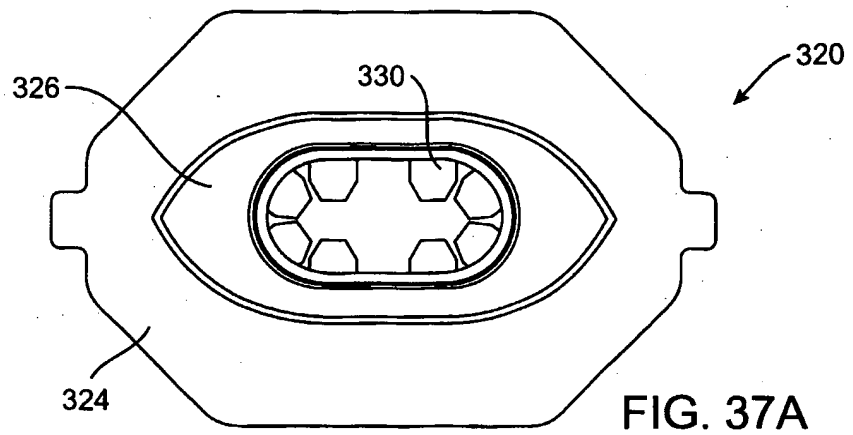


FIG. 33









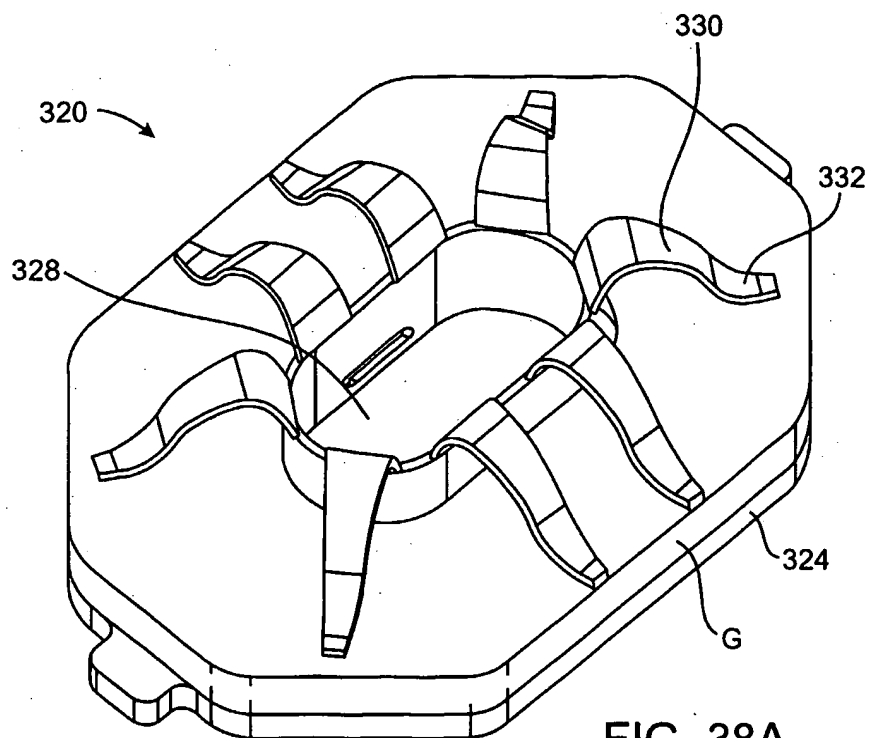


FIG. 38A

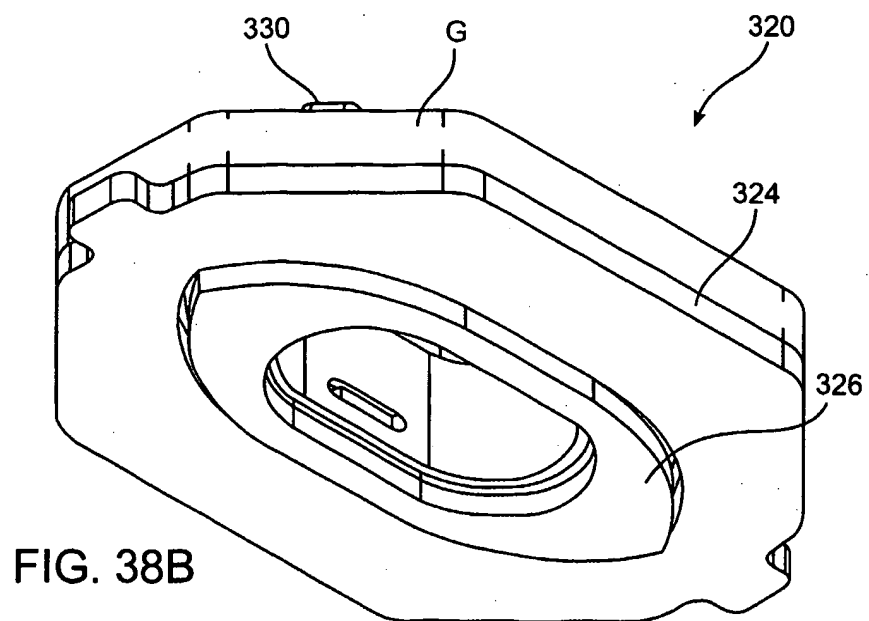


FIG. 38B

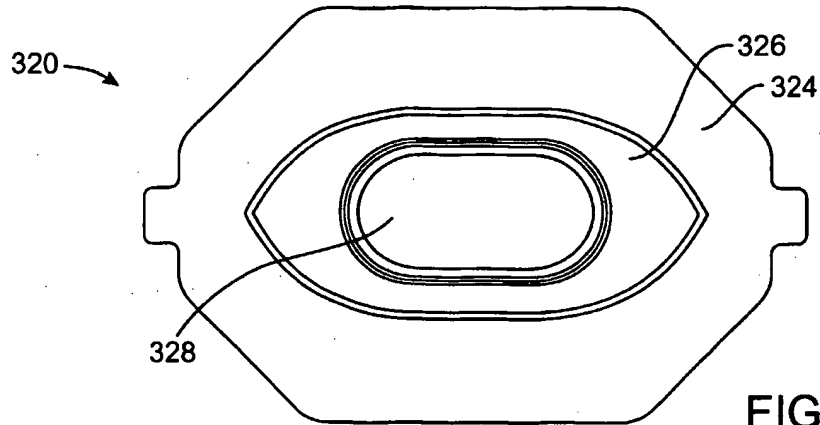


FIG. 39A

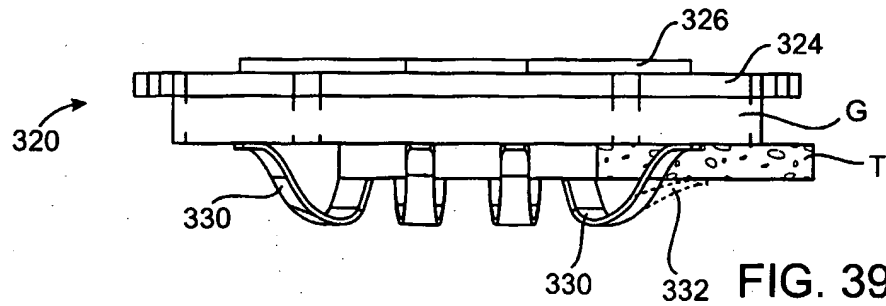


FIG. 39B

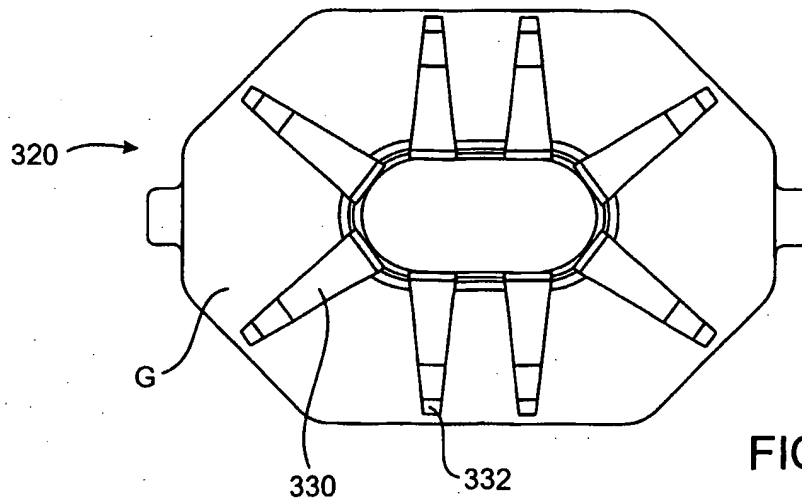


FIG. 39C

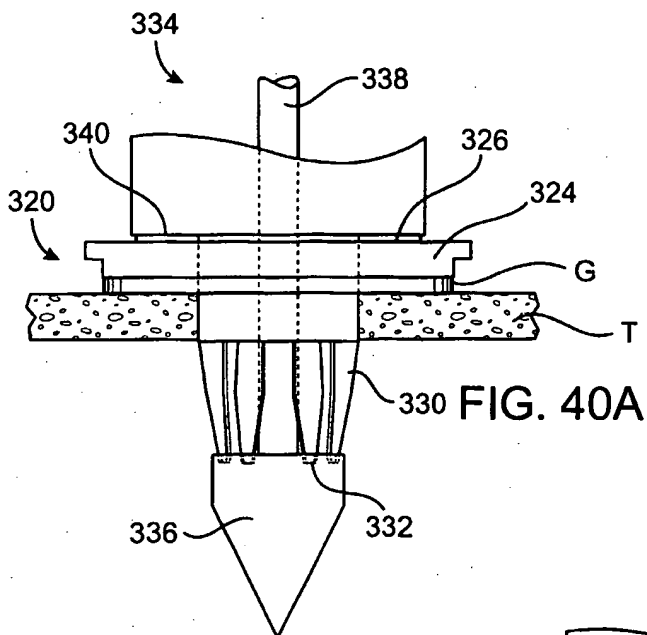


FIG. 40A

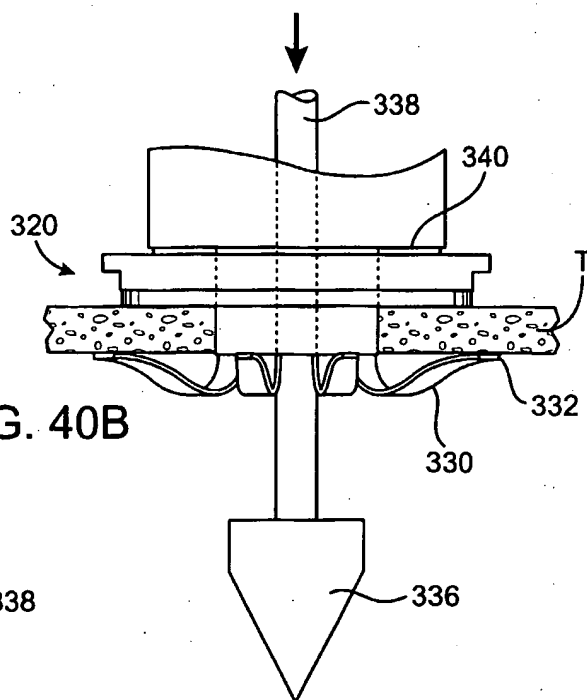


FIG. 40B

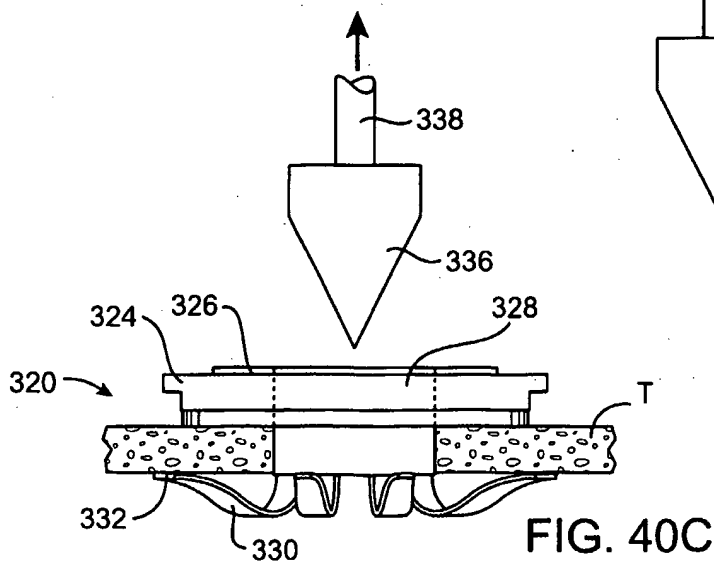


FIG. 40C

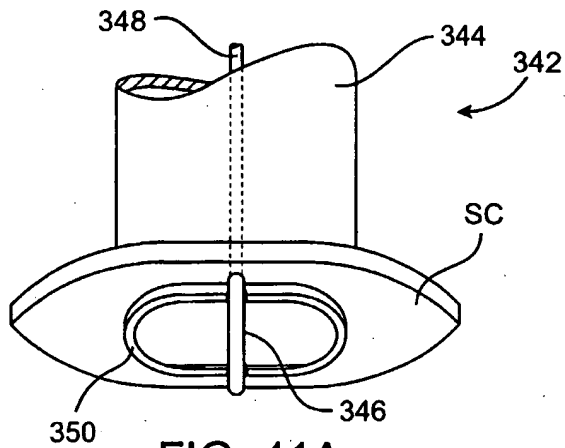


FIG. 41A

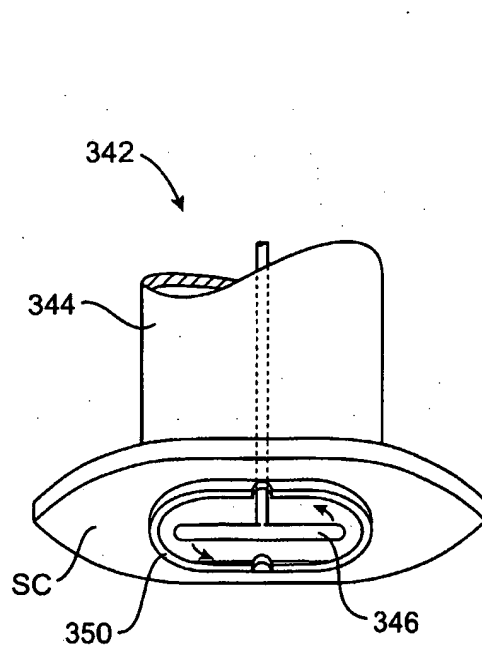


FIG. 41B

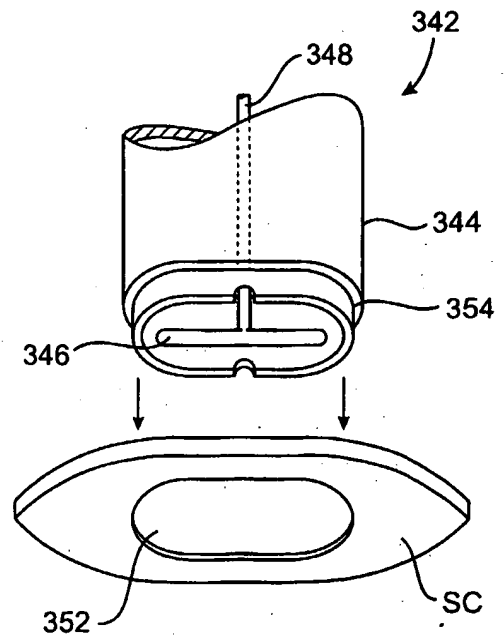


FIG. 41C

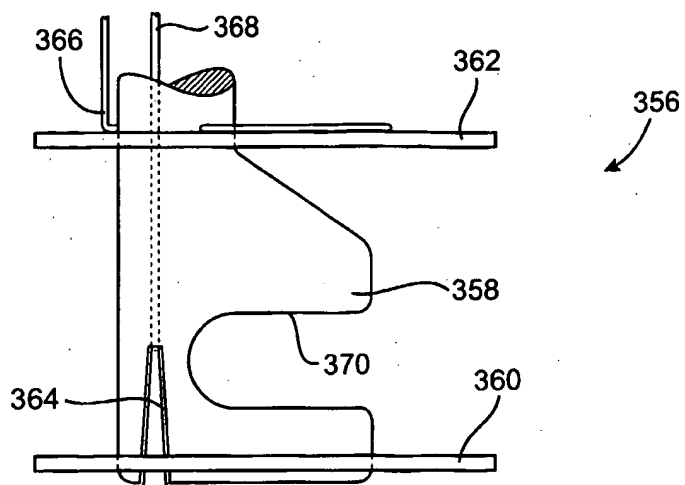


FIG. 42A

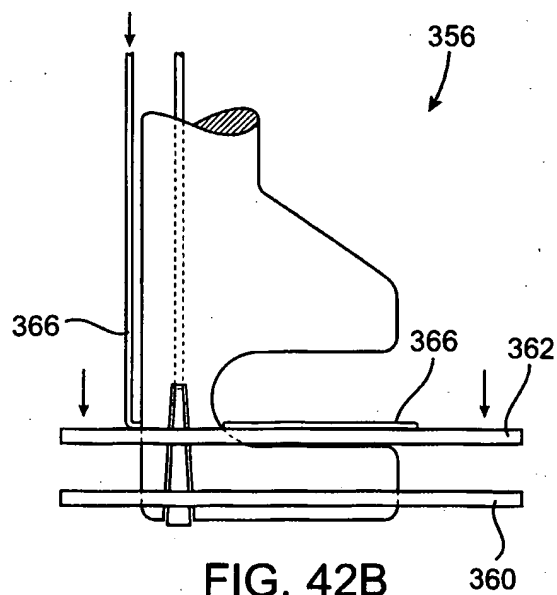


FIG. 42B

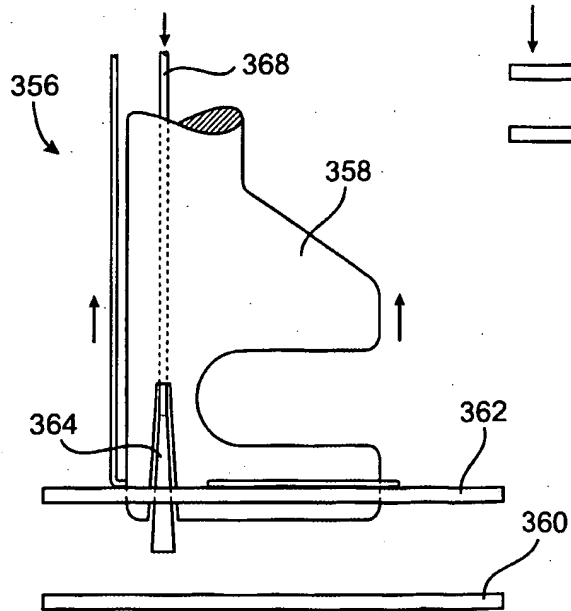
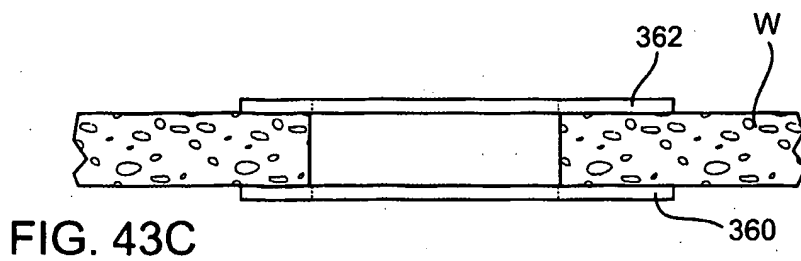
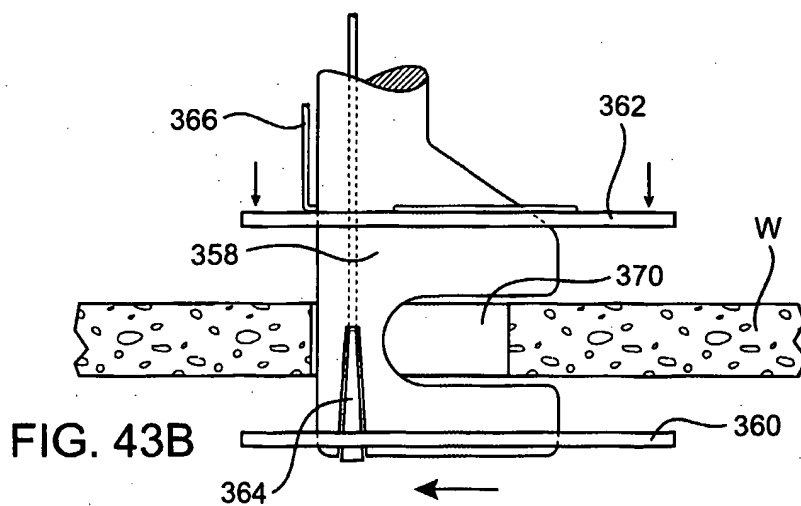
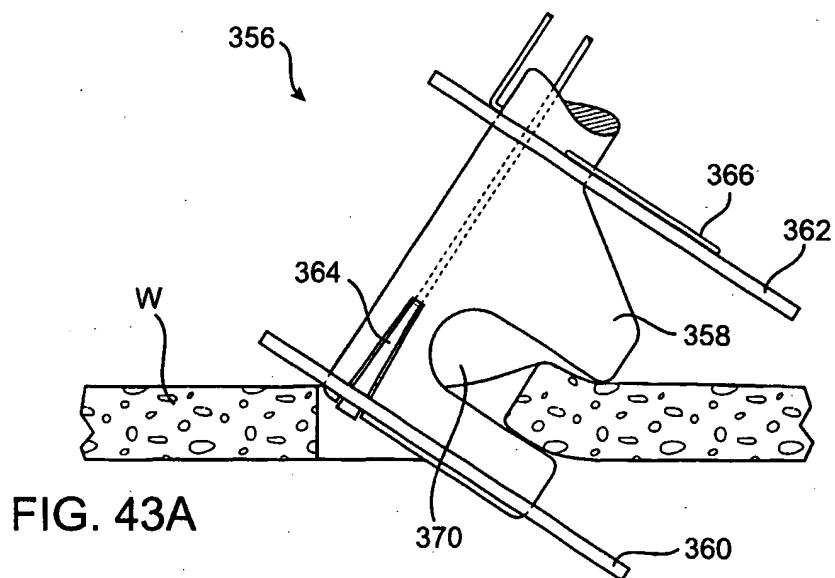


FIG. 42C



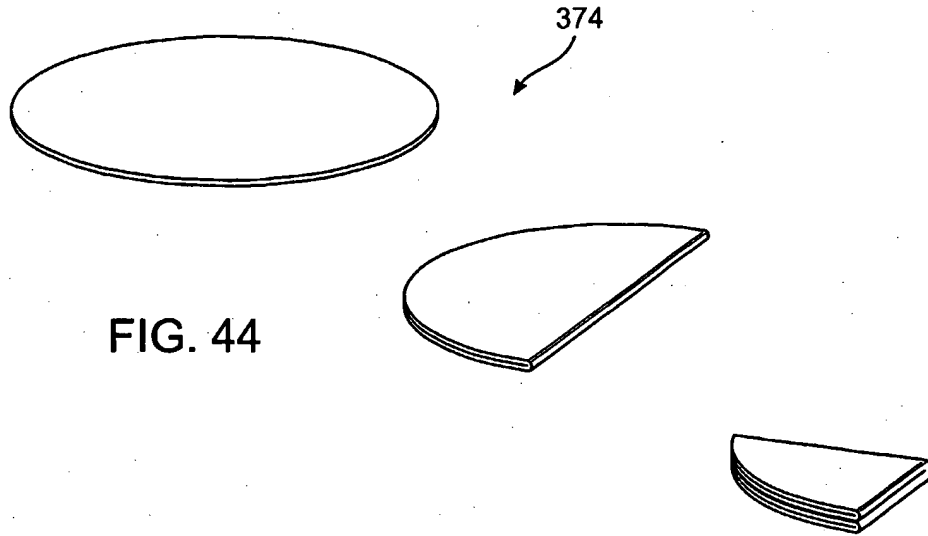


FIG. 44

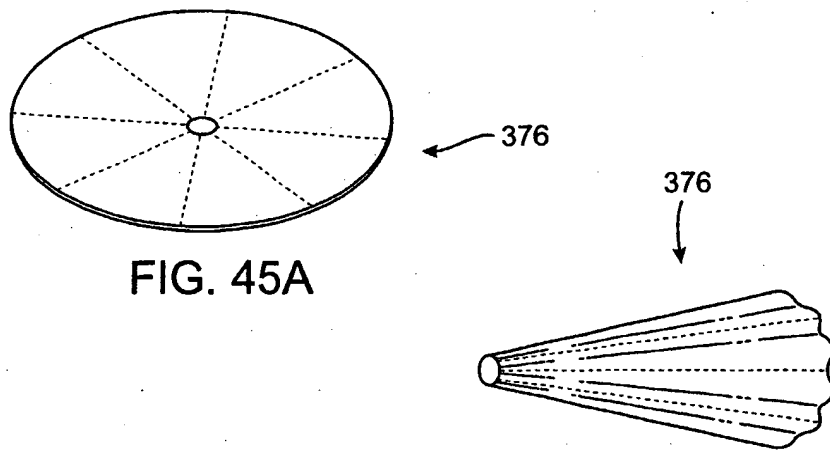


FIG. 45A

FIG. 45B

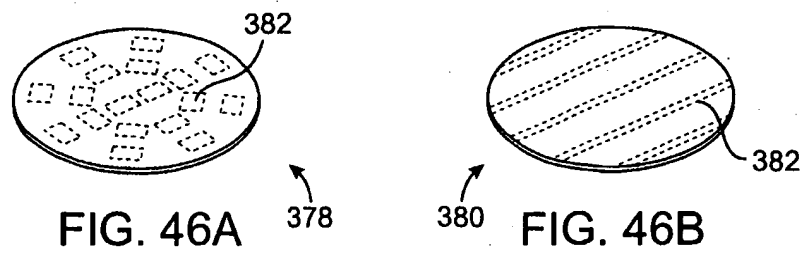


FIG. 46A

FIG. 46B

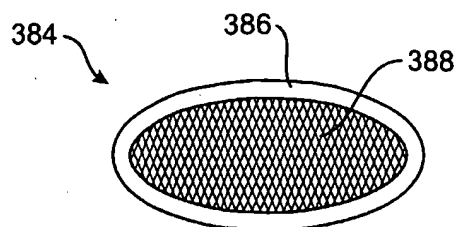


FIG. 46C

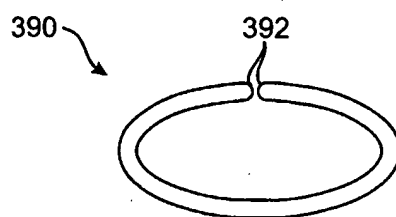


FIG. 46D

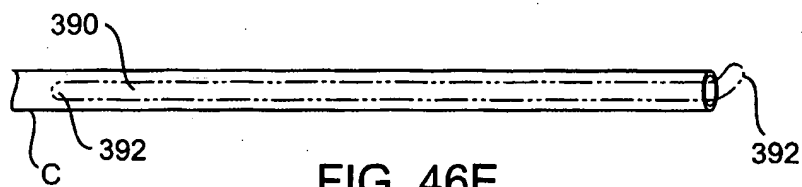


FIG. 46E

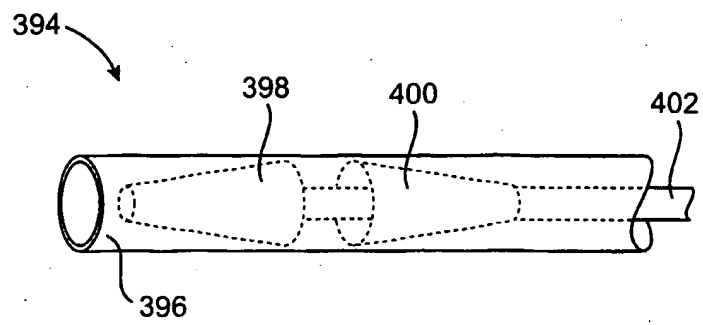


FIG. 47A

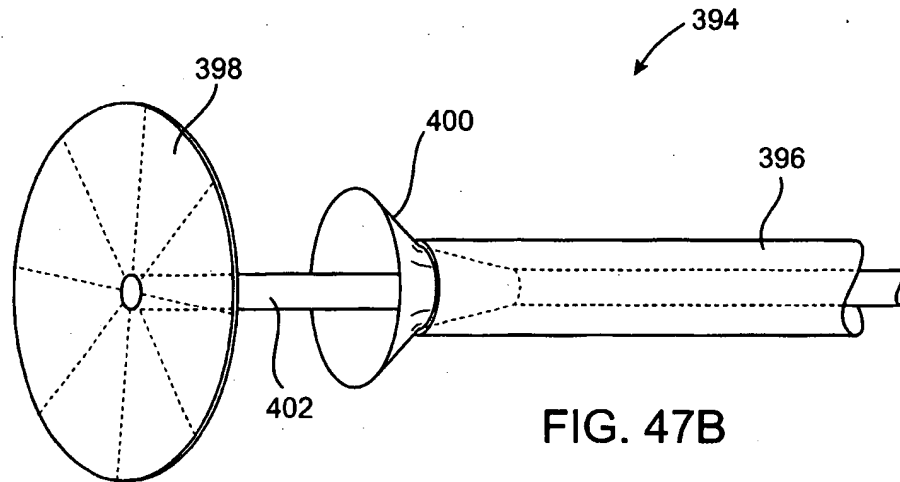


FIG. 47B

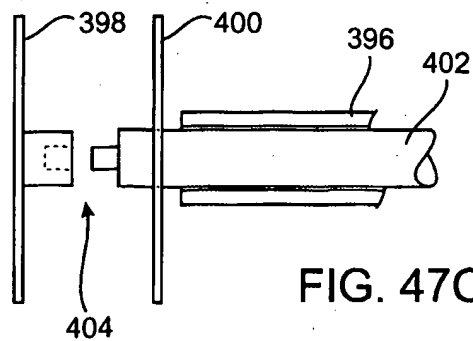


FIG. 47C

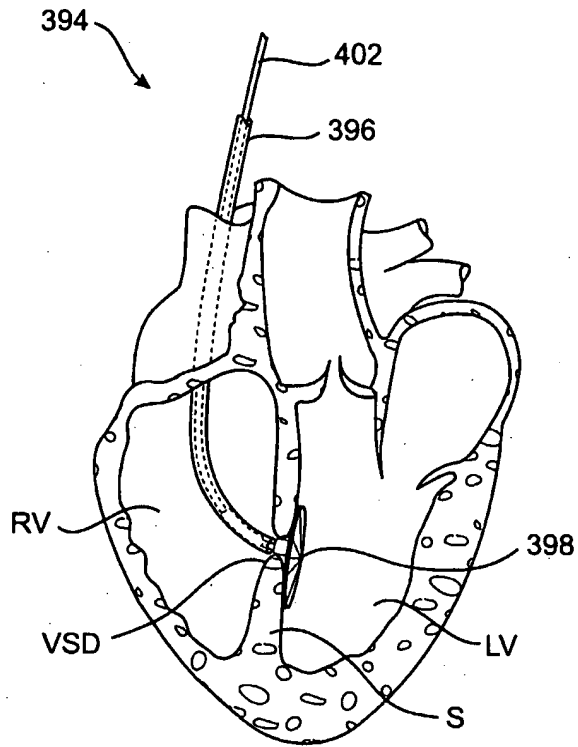


FIG. 48A

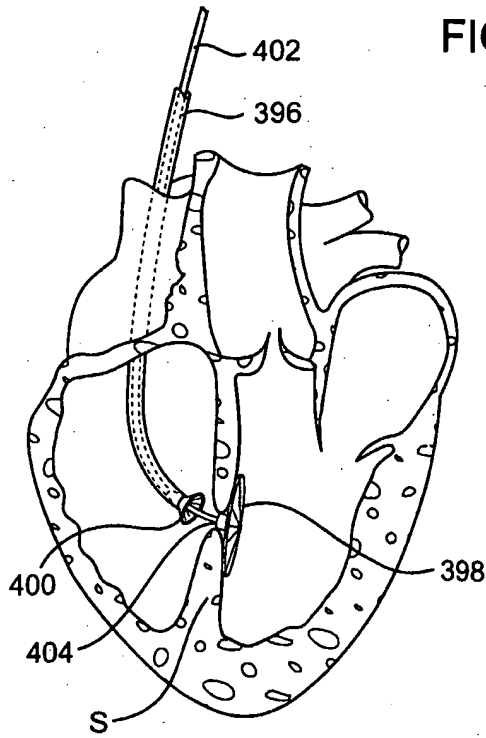


FIG. 48B

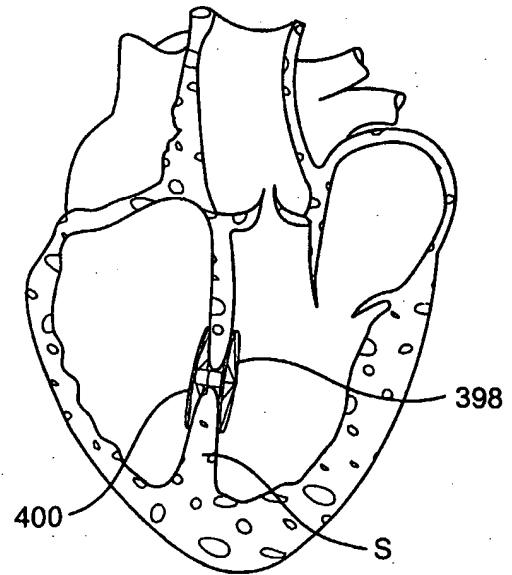


FIG. 48C

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US01/25113

A. CLASSIFICATION OF SUBJECT MATTER																				
IPC(7) :A61B 17/11 US CL :606/153 According to International Patent Classification (IPC) or to both national classification and IPC																				
B. FIELDS SEARCHED																				
Minimum documentation searched (classification system followed by classification symbols) U.S. : 606/151, 153, 215, 216																				
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched																				
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) EAST BRS search terms: anastomosis, magnetic																				
C. DOCUMENTS CONSIDERED TO BE RELEVANT																				
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.																		
X	US 5,690,656 A (COPE et al.) 25 November 1997, fig. 15.	1,2																		
----		-----																		
Y		7																		
X	OBORA, Y. et al., Nonsuture Microvascular Anastomosis Using Magnet Rings, Neurol. Med. Chir. (Tokyo), 1980, vol. 20, fig. 1.	18,19,21, 22,25,31, 32,43, 46-49																		
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.																				
<table border="0"> <tr> <td>* Special categories of cited documents:</td> <td>"I"</td> <td>later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</td> </tr> <tr> <td>"A" document defining the general state of the art which is not considered to be of particular relevance</td> <td>"X"</td> <td>document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</td> </tr> <tr> <td>"E" earlier document published on or after the international filing date</td> <td>"Y"</td> <td>document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</td> </tr> <tr> <td>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</td> <td>"G"</td> <td>document member of the same patent family</td> </tr> <tr> <td>"O" document referring to an oral disclosure, use, exhibition or other means</td> <td></td> <td></td> </tr> <tr> <td>"P" document published prior to the international filing date but later than the priority date claimed</td> <td></td> <td></td> </tr> </table>			* Special categories of cited documents:	"I"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention	"A" document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone	"E" earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art	"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"G"	document member of the same patent family	"O" document referring to an oral disclosure, use, exhibition or other means			"P" document published prior to the international filing date but later than the priority date claimed		
* Special categories of cited documents:	"I"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention																		
"A" document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone																		
"E" earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art																		
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"G"	document member of the same patent family																		
"O" document referring to an oral disclosure, use, exhibition or other means																				
"P" document published prior to the international filing date but later than the priority date claimed																				
Date of the actual completion of the international search 19 OCTOBER 2001		Date of mailing of the international search report 20 DEC 2001																		
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-9230		Authorized officer JULIAN W. WOO <i>Julian W. Woo</i> Telephone No. (703) 308-0421																		

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☒ FADED TEXT OR DRAWING
- ☒ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☐ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.